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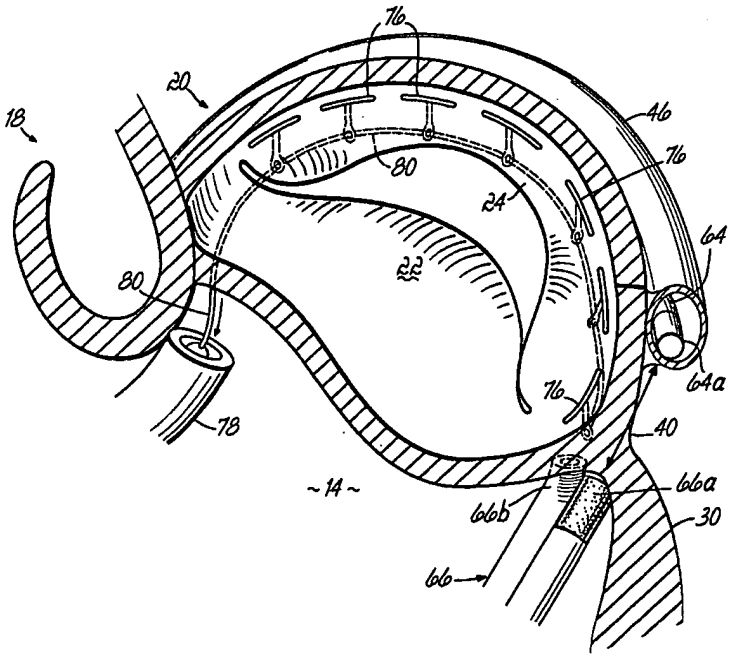

(57) Abstract: Catheter based systems and methods for securing tissue including the annulus (40) of a mitral valve (20). The systems and methods employ catheter based techniques and devices to plicate tissue and perform an annuloplasty. Magnets (64a, 66a) may be used for guidance in deploying fasteners (76) from a catheter (66). The fasteners are cinched with a flexible tensile member (80).

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TISSUE FASTENING SYSTEMS AND METHODS UTILIZING MAGNETIC GUIDANCE

Field of the Invention

The present invention relates generally to techniques for treating mitral valve insufficiencies such as mitral valve leakage due to prolapse, papillary muscle dysfunction, or annular dilation. More particularly, the present invention relates to systems and methods for treating a leaking mitral valve in a minimally invasive manner. Various aspects of the invention further pertain more generally to magnetic guidance and/or fastener delivery systems used for approximating or otherwise operating on tissue.

Background of the Invention

Congestive heart failure (CHF), which is often associated with an enlargement of the heart, is a leading cause of death. As a result, the market for the treatment of CHF is becoming increasingly prevalent. For instance, the treatment of CHF is a leading expenditure of Medicare and Medicaid dollars in the United States. Typically, the treatment of CHF enables many who suffer from CHF to enjoy an improved quality of life.

Referring initially to Fig. A, the anatomy of a heart 10, specifically the left side of the heart 10, includes a left atrium (LA) 12 and a left ventricle (LV) 14. An aorta 16 receives blood from left ventricle 14 through an aortic valve 18, which serves to prevent regurgitation of blood back into left ventricle 14. A mitral valve 20 is positioned between left atrium 12 and left ventricle 14, and allows one-way flow of blood from the left atrium 12 to the left ventricle 14.

Mitral valve 20, which will be described below in more detail, includes an anterior leaflet 22 and a posterior leaflet 24 that are coupled to cordae tendonae 26 which serve as "tension members" that prevent the leaflets 22, 24 of mitral valve 20 from going past their closing point and prolapsing back into the left atrium. When left ventricle 14 contracts during systole, cordae tendonae 26 limit the upward (toward the left atrium) motion of the anterior and posterior leaflets past the point at which the anterior and posterior leaflets 22, 24 meet and seal to prevent backflow from the left ventricle to the left atrium ("mitral regurgitation" or "mitral insufficiency"). Cordae tendonae 26 arise from a columnae carnae or, more specifically, a musculi papillares (papillary muscles) 28 of the columnae carnae. In various figures herein, some anatomical features have been deleted solely for clarity.

Fig. B is a cut-away top-view representation of mitral valve 20 and aortic valve 18. Anterior leaflet 22 and posterior leaflet 24 of the mitral valve 20 are generally thin, flexible membranes. When mitral valve 20 is closed (as shown in Fig. B), anterior leaflet 22 and posterior leaflet 24 are generally aligned and contact one another along a "line of coaptation" several millimeters back from their free edges, to create a seal that prevents mitral regurgitation. Alternatively, when mitral valve 20 is opened, blood flows downwardly through an opening created between anterior leaflet 22 and posterior leaflet 24 into left ventricle 14.

Many problems relating to mitral valve 20 may occur and may cause many types of ailments. Such problems include, but are not limited to, mitral regurgitation. Mitral regurgitation, or leakage, is the backflow of blood from left ventricle 14 into the left atrium 12 due to an imperfect closure or prolapse of mitral valve 20. That is, leakage often occurs when the anterior and posterior leaflets to not seal against each other, resulting in a gap 32 between anterior leaflet 22 and posterior leaflet 24.

In general, a relatively significant gap 32 may exist between anterior leaflet 22 and posterior leaflet 24 (as shown in Fig. C) for a variety of different reasons. For example, a gap 32 may exist due to congenital malformations, because of ischemic disease, or because the heart 10 has been damaged by a previous heart attack. A gap 32 may also be created when congestive heart failure, *e.g.*, cardiomyopathy, or some other type of distress which causes a heart to be enlarged. Enlargement of the heart can result in dilation (stretching) of the mitral annulus. This enlargement is usually limited to the posterior valve annulus and is associated with the posterior leaflet, because the anterior annulus is a relatively rigid fibrous structure. When the posterior annulus enlarges, it causes the posterior leaflet to move away from the anterior leaflet, causing a gap because the two leaflets no longer form proper coaptation, and this results in leakage of blood through the valve, or regurgitation.

Leakage through mitral valve 20 generally causes a heart 10 to operate less efficiently, as the heart 10 must pump blood both out to the body via the aorta, and also back (in the form of mitral regurgitation) back into the left atrium. Leakage through mitral valve 20, or general mitral insufficiency, is thus often considered to be a precursor to CHF or a cause of progressive worsening of heart failure. There are generally different levels of symptoms associated with heart failure. Such levels are classified by the New York Heart Association (NYHA) functional classification system. The levels range from a Class 1 level

which is associated with an asymptomatic patient who has substantially no physical limitations to a Class 4 level which is associated with a patient who is unable to carry out any physical activity without discomfort, and has symptoms of cardiac insufficiency even at rest. In general, correcting or reducing the degree of mitral valve leakage may be successful in allowing the NYHA classification grade of a patient to be reduced. For instance, a patient with a Class 4 classification may have his classification reduced to Class 3 or Class 2 and, hence, be relatively comfortable at rest or even on mild physical exertion. By eliminating the flow of blood backwards into the left atrium, therapies that reduce mitral insufficiency reduce the work load of the heart and may prevent or slow the worsening of heart function and congestive heart failure symptoms that is common when a significant degree of mitral insufficiency remains uncorrected.

Treatments used to correct for mitral valve leakage or, more generally, CHF, are typically highly invasive, open-heart surgical procedures as described below. In extreme cases, this may include implantation of a ventricular assist device such as an artificial heart in a patient whose own heart is failing. The implantation of a ventricular assist device is often expensive, and a patient with a ventricular assist device must be placed on extended anti-coagulant therapy. As will be appreciated by those skilled in the art, anti-coagulant therapy reduces the risk of blood clots being formed, as for example, within the ventricular assist device. While reducing the risks of blood clots associated with the ventricular assist device is desirable, anti-coagulant therapies may increase the risk of uncontrollable bleeding in a patient, *e.g.*, as a result of a fall, which is not desirable.

Rather than implanting a ventricular assist device, bi-ventricular pacing devices similar to pace makers may be implanted in some cases, *e.g.*, cases in which a heart beats inefficiently in a particular asynchronous manner. While the implantation of a bi-ventricular pacing device may be effective, not all heart patients are suitable for receiving a bi-ventricular pacing device. Further, the implantation of a bi-ventricular pacing device is expensive, and is generally not effective in significantly reducing or eliminating the degree of mitral regurgitation.

Open-heart surgical procedures which are intended to correct for mitral valve leakage, specifically, can involve the implantation of a replacement valve. Valves from animals, *e.g.*, pigs, may be used to replace a mitral valve 20 in a human. While the use of a pig valve may relatively successfully replace a mitral valve, such valves generally wear out, thereby requiring additional open surgery at

a later date. Mechanical valves, which are less likely to wear out, may also be used to replace a leaking mitral valve. However, when a mechanical valve is implanted, there is an increased risk of thromboembolism, and a patient is generally required to undergo extended anti-coagulant therapies.

A less invasive surgical procedure involves heart bypass surgery associated with a port access procedure. For a port access procedure, the heart may be accessed by cutting between ribs or sometimes removing parts of one or more ribs, as opposed to dividing the sternum to open the entire chest of a patient. In other words, the opening occurs between the ribs in a port access procedure, rather than opening a patient's sternum.

One open-heart surgical procedure that is particularly successful in correcting for mitral valve leakage and, in addition, mitral regurgitation, is an annuloplasty procedure. During an annuloplasty procedure, a medical device -- an annuloplasty ring -- may be implanted surgically on the left atrial side of mitral annulus (the attachment of the base of the mitral valve to the heart) to cause the size of a dilated mitral valve annulus to be reduced to a relatively normal size, and specifically to move the posterior leaflet closer to the anterior leaflet to aid anterior – posterior leaflet coaptation and thus improve the quality of mitral valve closure and significantly reduce the amount of mitral insufficiency. Fig. D is a schematic representation of an annuloplasty ring 34. An annuloplasty ring 34 is shaped approximately like the contour of a normal mitral valve 20. That is, annuloplasty ring 34 is shaped substantially like the letter "D." Typically, annuloplasty ring 34 may be formed from a rod or tube of biocompatible material, *e.g.*, plastic, that has a DACRON mesh covering.

In order for annuloplasty ring 34 to be implanted, a surgeon surgically attaches annuloplasty ring 34 to the mitral valve on the atrial side of the mitral valve 20. Conventional methods for installing ring 34 require open-heart surgery which involve opening a patient's sternum and placing the patient on a heart bypass machine. As shown in Fig. E, annuloplasty ring 34 is sewn to a posterior leaflet 24 and an anterior leaflet 22 of a top portion of mitral valve 20. In sewing annuloplasty ring 34 onto mitral valve 20, a surgeon generally sews the straight side of the "D" to the fibrous tissue located at the junction between the posterior wall of the aorta and the base of the anterior mitral valve leaflet. As the curved part of the ring is sewn to the posterior aspect of the annulus, the surgeon alternately acquires a relatively larger amount of tissue from the mitral annulus, *e.g.*, a one-eighth inch bite of tissue, using a needle and thread, compared to a

relatively smaller bite taken of the fabric covering of annuloplasty ring 34. Once a thread has loosely coupled annuloplasty ring 34 to mitral valve tissue, annuloplasty ring 34 is slid into contact with the mitral annulus 40 such that the tissue of the posterior mitral annulus that was previously stretched out, *e.g.*, due to an enlarged heart, is effectively reduced in circumference and pulled forwards towards the anterior mitral leaflet by the tension applied by annuloplasty ring 34 by the thread that binds the annuloplasty ring 34 to the mitral annulus tissue. As a result, a gap, such as gap 32 of Fig. C, between anterior leaflet 22 and posterior leaflet 24 during ventricular contraction (systole) may be reduced and even substantially closed off in many cases thereby significantly reducing or even eliminating mitral insufficiency. After the mitral valve 20 is shaped by ring 34, the anterior and posterior leaflets 22, 24 will reform typically by pulling the posterior leaflet forward to properly meet the anterior leaflet and create a new contact line that will enable mitral valve 20 to appear and to function properly.

Once implanted, tissue generally grows over annuloplasty ring 34, and a line of contact between annuloplasty ring 34 and mitral valve 20 will essentially enable mitral valve 20 to appear and function normally. Although a patient who receives annuloplasty ring 34 may be subjected to anti-coagulant therapies, the therapies are not extensive, as a patient is only subjected to the therapies for a matter of weeks, *e.g.*, until tissue grows over annuloplasty ring 34.

A second surgical procedure which is generally effective in reducing mitral valve leakage associated with prolapse of the valve leaflets involves placing a single edge-to-edge suture in the mitral valve 20 that apposes the mid-portions of anterior and posterior leaflets. With reference to Fig. F, such a surgical procedure, *e.g.*, an Alfieri stitch procedure or a bow-tie repair procedure, will be described. An edge-to-edge stitch 36 is used to stitch together an area at approximately the center of the gap 32 defined between an anterior leaflet 22 and a posterior leaflet 24 of a mitral valve 20. Once stitch 36 is in place, stitch 36 is pulled in to form a suture which holds anterior leaflet 22 against posterior leaflet 24, as shown. By reducing the size of gap 32, the amount of leakage through mitral valve 20 may be substantially reduced.

Although the placement of edge-to-edge stitch 36 is generally successful in reducing the amount of mitral valve leakage through gap 32, edge-to-edge stitch 36 is conventionally made through open-heart surgery. In addition, the use of edge-to-edge stitch 36 is generally not suitable for a patient with an enlarged, dilated heart, as blood pressure causes the heart to dilate outward, and

may put a relatively large amount of stress on edge-to-edge stitch 36. For instance, blood pressure of approximately 120/80 or higher is typically sufficient to cause the heart 10 to dilate outward to the extent that edge-to-edge stitch 36 may become undone, or tear mitral valve tissue.

Another surgical procedure which reduces mitral valve leakage involves placing sutures along a mitral valve annulus around the posterior leaflet. A surgical procedure which places sutures along a mitral valve 20 will be described with respect to Fig. G. Sutures 38 are formed along the annulus 40 of a mitral valve 20 that surrounds the posterior leaflet 24 of mitral valve 20. These sutures may be formed as a double track, *e.g.*, in two "rows" from a single strand of suture material 42. Sutures 38 are tied off at approximately a central point (P2) of posterior leaflet 24. Pledgets 44 are often positioned under selected sutures, *e.g.*, at the two ends of the sutured length of annulus or at the central point P2, to prevent sutures 38 from tearing through annulus 40. When sutures 38 are tightened and tied off, the circumference of the annulus 40 may effectively be reduced to a desired size such that the size of a gap 32 between posterior leaflet 24 and an anterior leaflet 22 may be reduced.

The placement of sutures 38 along annulus 40, in addition to the tightening of sutures 38, is generally successful in reducing mitral valve leakage. However, the placement of sutures 38 is conventionally accomplished through open-heart surgical procedures. That is, like other conventional procedures, a suture-based annuloplasty procedure is invasive.

While invasive surgical procedures have proven to be effective in the treatment of mitral valve leakage, invasive surgical procedures often have significant drawbacks. Any time a patient undergoes open-heart surgery, there is a risk of infection. Opening the sternum and using a cardiopulmonary bypass machine has also been shown to result in a significant incidence of both short and long term neurological deficits. Further, given the complexity of open-heart surgery, and the significant associated recovery time, people who are not greatly inconvenienced by CHF symptoms, *e.g.*, people at a Class 1 classification, may choose not to have corrective surgery. In addition, people who most need open heart surgery, *e.g.*, people at a Class 4 classification, may either be too frail or too weak to undergo the surgery. Hence, many people who may benefit from a surgically repaired mitral valve may not undergo surgery.

Fig. H illustrates the cardiac anatomy, highlighting the relative position of the coronary sinus (CS) 46 running behind the posterior leaflet 24 of

the mitral valve 20. Fig. 1 is an illustration of the same anatomy but schematically shows a cinching device 48 which is placed within the CS 46 using a catheter system 50, with distal, mid, and proximal anchors 52a, 52b, 52c within the lumen of the CS 46 to allow plication of the annulus 40 via the CS 46. In practice, these anchors 52a-c are cinched together, i.e., the distance between them is shortened by pulling a flexible tensile member 54 such as a cable or suture with the intent being to shorten the valve annulus 40 and pull the posterior leaflet 24 closer to the anterior leaflet 22 in a manner similar to an annuloplasty procedure. Unfortunately, since the tissue which forms the CS 46 is relatively delicate, the anchors 52a-c are prone to tear the tissue during the cinching procedure, and the effect on the mitral annulus may be reduced by the position of the coronary sinus up more towards the left atrium rather than directly over the mitral annulus itself. Other minimally invasive techniques have been proposed and/or developed but have various drawbacks related to such factors as effectiveness and/or cases and accuracy of catheter-based implementation.

Therefore, there remains a need for improved minimally invasive treatments for mitral valve leakage. Specifically, what is desired is a method for decreasing the circumference of the posterior mitral annulus, moving the posterior leaflet forwards towards the anterior leaflet and thereby reducing leakage between an anterior leaflet and a posterior leaflet of a mitral valve, in a manner that does not require conventional surgical intervention.

Summary of the Invention

The invention provides a method of modifying an annulus of a heart valve in a first general aspect. The annulus lies generally below the coronary sinus at least at one location. The method comprises fastening the coronary sinus to the annulus to bring the annulus closer to the coronary sinus at least at the one location, and then reducing regurgitation by modifying the annulus. For example, the annulus may be modified by shortening the circumferential length (i.e., the arc length) of the annulus or changing the shape or other physical characteristic of the annulus. Fastening the coronary sinus can further comprise inserting a first guide element into the coronary sinus, directing a second guide element into the left ventricle so it lies under and/or adjacent to the annulus, securing the first and second guide elements together, and applying a fastener between the annulus and the coronary sinus.

The guide elements may be removed after applying the fastener, and therefore act as a temporary anchor for the fastener delivery device and/or the tissue to be secured. Alternatively, the guide elements, or portions thereof, may be left in place. The guide elements may comprise mechanical fasteners or other types of fasteners such as magnets (i.e., magnetic elements), or combinations thereof. One guide element of the invention comprises first and second spaced apart magnets on the distal support portion of a catheter. Repelling poles of the magnets face each other to create a circumferential virtual pole emanating around the gap formed between the spaced apart magnets. Securing the first and second guide elements together can further comprise magnetically attracting the first and second guide elements together. The same catheter device may be used to direct the second guide element and apply the fastener. In addition, the method can include applying a second fastener to the annulus, coupling the first and second fasteners together, and reducing the distance between the first and second fasteners to reduce the circumference of the annulus. In this case applying the first and second fasteners can occur through the same catheter device. More particularly, the method can involve serially applying the first and second fasteners through one lumen in a catheter device or, as another example, applying the first and second fasteners through different lumens of the same catheter device. In another aspect of the invention, at least one flexible tensile member is used to couple the first and second fasteners together and the flexible tensile member is tensioned to reduce the distance between the first and second fasteners. Shortening the circumferential length of the annulus can further comprise fastening a flexible fabric to the annulus and shortening the circumferential length of the flexible fabric.

In another general aspect, a method of modifying an annulus of a heart valve comprises applying first and second fasteners on opposite sides of the annulus through at least one catheter thereby holding heart tissue between the first and second fasteners, applying third and fourth fasteners on opposite sides of the annulus through at least one catheter thereby holding heart tissue between the third and fourth fasteners. As with the fasteners applied in the various aspects of this invention, different chateters or different catheter portions may be used to apply the different fasteners or the same catheter may be used. The first and second fasteners are coupled and the third and fourth fasteners are coupled using at least one flexible tensile member. The distance between adjacent ones of at

least two of the first, second, third and fourth fasteners is reduced by applying tension to the flexible tensile member thereby modifying the annulus.

The first, second, third, and fourth fasteners can include at least one magnet and/or at least one mechanical fastening element, such as a mechanical element configured to penetrate and engage with tissue. In addition, the method can include using at least one magnet delivered through a catheter to guide at least one of the fasteners into position. As one option, the guiding magnet may be removed after guiding the fastener or fasteners into position. The fastener or fasteners may be delivered through the guiding magnet.

In another general aspect of the invention, a heart valve annulus is modified by delivering a first fastener through a catheter into the coronary sinus, and delivering a second fastener through a catheter to at least one of two locations, the two locations being 1) generally above the annulus in the left atrium, and 2) generally below the annulus in the left ventricle. The fasteners are secured to the annulus and the distance between the first and second fasteners is reduced to thereby modify the annulus with the respectively delivered fasteners. In another aspect, a flexible tensile member is connected between the fasteners, and the distance between the fasteners is reduced by tensioning the flexible tensile member to modify the annulus. The flexible tensile member may be locked into position with respect to the fasteners by applying a crimp member or other locking element, which may or may not be part of a fastener, to the flexible tensile member. In another embodiment, the fasteners are held in spaced apart positions while securing the fasteners to heart tissue at the two locations. The fasteners are biased toward each other to reduce the distance between adjacent fasteners and modify the annulus with the respectively delivered fasteners. Biasing the fasteners can further comprise magnetically attracting adjacent fasteners toward one another or, as another example, spring biasing adjacent fasteners toward one another. As one option, pressurized air may be used to hold the fasteners in the spaced apart positions prior to biasing the fasteners together. In another aspect, radio frequency energy or any other suitable method is used to form an aperture in the heart tissue in order to apply the fastener(s) through the tissue.

The invention further provides a system for modifying an annulus of a heart valve comprising a first catheter, a first magnet coupled with the first catheter in such a manner that the first catheter is operative to deliver the first magnet adjacent to the annulus. The system further includes a second catheter and a second magnet coupled with the second catheter in such a manner that the

second catheter is operative to deliver the second magnet adjacent to the annulus. A fastener delivery portion may be operatively associated with the first catheter. The fastener delivery portion may be coupled at predetermined angle relative to an axis of magnetic attraction between the first and second magnets.

The fastener delivery portion can be movable relative to the first and second magnets so as to enable delivery of a fastener to a desired position. The system can further comprise a plurality of fastener delivery portions configured to deliver respective fasteners at spaced apart locations along the annulus. The plurality of fasteners may be coupled together with at least one flexible tensile member such that the flexible tensile member is capable of drawing the fasteners together and thereby modifying the annulus.

In another embodiment, a catheter system for modifying an annulus of a heart valve comprises a catheter having at least one lumen and first and second fasteners coupled together by an elongate flexible member such that the first fastener is movable along the elongate flexible member to a position closer to the second fastener. An actuation device is coupled in a releasable manner to the elongate flexible member and adapted to pull the elongate flexible member to thereby reduce the distance between the first and second fasteners. A coupling secures the elongate flexible member in a locked position relative to the first and second fasteners. The first and second fasteners can further comprise magnets and/or mechanical fasteners, such as fasteners having projections configured to penetrate heart tissue. The coupling further can further comprise a crimpable or other type of locking member. The first and second fasteners may be further coupled together by a length adjustable member configured to allow the distance between the first and second fasteners to be shortened as the actuation mechanism pulls the flexible tensile member. The length adjustable member can include first and second telescoping portions coupled together or, as another example, a generally accordion-shaped section.

In another embodiment, a catheter system for modifying an annulus of a heart valve comprises a catheter having at least one lumen and first and second fasteners coupled together by a flexible tensile member such that the first fastener is movable along the flexible tensile member relative to the second fastener. A first fastener delivery portion is coupled with the catheter and delivers the first fastener into a first position proximate the annulus. A second fastener delivery portion is coupled with the catheter and moves with respect to the first fastener delivery portion. The second fastener delivery portion delivers

the second fastener into a second position proximate the annulus and spaced from the first position. This system can further include a third fastener coupled to the flexible tensile member, and a third fastener delivery portion coupled with the catheter and capable of delivering the third fastener into a third position proximate the annulus and spaced from the first and second positions. The system can also include first and second fastener drive members coupled respectively with the first and second fastener delivery portions, and being selectively movable to drive the first and second fasteners into the tissue proximate the annulus.

The systems of this invention can include fastener delivery portions comprising at least one spring and drive member each located, for example, at the distal end of a catheter device. Such fastener delivery portions can force the fastener(s) into tissue proximate the annulus. Catheters used in the invention can include a magnet at the distal end for coupling with another magnet located proximate the annulus thereby stabilizing the catheter during delivery of the fastener(s). A lock member may be secured to the flexible tensile member and used to selectively prevent relative movement between the delivered fasteners.

In another embodiment, a catheter system for modifying an annulus of a heart valve includes a catheter having at least one lumen and first and second fasteners coupled together by a flexible tensile member and adapted to be secured to heart tissue proximate the annulus. A rod is movable between a compact state within the lumen and an expanded state outside of the lumen. The first and second fasteners are further coupled to the rod such that the first fastener is movable along the rod relative to the second fastener by applying tension to the flexible tensile member. The rod may be generally C-shaped in the expanded state so as to follow the annulus. A third fastener may be coupled for movement along the rod and adapted to be secured to heart tissue proximate the annulus. A second flexible tensile member can be secured to the third fastener. The third fastener may then be moved along the rod relative to the second fastener by applying tension to the second flexible tensile member. A magnet can be connected to the rod and adapted to magnetically couple with a magnet in the coronary sinus for stabilizing the position of the rod as the fasteners are secured to the heart tissue.

Another catheter system for modifying an annulus of a heart valve generally comprises a catheter having at least one lumen and first and second fasteners adapted to be secured to heart tissue proximate the annulus. At least one flexible tensile member couples the first and second fasteners together. A

locking device activated by way of a catheter to fix the fastener positions is provided. For example, a locking element delivery device is deployable through a catheter, which may be the same catheter as a fastener delivery catheter, or a different catheter. For example, the locking element can be a crimp and a compression applying mechanism deployed from the catheter can be configured to compress the crimp onto the flexible tensile member after the fasteners are pulled toward one another with the flexible tensile member to modify the annulus. Other types of locking elements may, for example, include spring elements or other biased elements which are held in an open position and then released into a closed or locked position onto one or more flexible tensile members. Any locking element which is selectively lockable onto a flexible tensile member may be used as appropriate for the application. A flexible tensile member releasing device is provided which releases the flexible tensile member from the catheter system is also provided. This may involve a mechanical disconnection mechanism, such as threads or other connectors, or a cutting mechanism associated which cuts the flexible tensile member after locking takes place, such as mentioned above. A third fastener is adapted to be secured to the heart tissue, and separate flexible tensile members may be connected with each of the fasteners and threaded through the locking element, such as a crimp. It will be appreciated that the term " flexible tensile members", as used herein, will apply to separate portions of a single element, such as a suture strand, wire, cable or other solid or hollow elongate structure which may be looped back on itself and locked in place, and it will also apply to separate elements altogether.

Another catheter system for modifying an annulus of a heart valve comprises first, second and third fasteners adapted to be secured to heart tissue proximate the annulus. First, second and third flexible tensile members are respectively connectable to the first, second and third fasteners. A generally V-shaped valve support member is provided having a pair of legs movable between a compact state suitable for carrying the valve support member within a catheter and an expanded state in which the legs are more separated. A free end of each leg includes respective first and second eyelets receiving the first and second flexible tensile members and an apex between the pair of legs including a third eyelet receiving the third flexible tensile member. First, second and third crimp members may be provided for respectively securing the first, second and third flexible tensile members with respect to the first, second and third eyelets after at

least one of the flexible tensile members is pulled tight to modify the shape of the annulus.

Various additional features, advantages, and aspects of the invention will become more readily apparent to those of ordinary skill in the art upon review of the following detailed description of the illustrative embodiments taken in conjunction with the accompanying drawings.

Brief Description of the Drawings

Fig. A is a cutaway of the left side of the heart showing the internal muscular and valve structure.

Fig. B is a top view showing the normal positions of a mitral valve and adjacent aortic valve.

Fig. C is a top view similar to Fig. B but illustrating the mitral valve in a prolapsed condition in which the posterior leaflet is separated from the anterior leaflet.

Fig. D is an elevational view illustrating a conventional annuloplasty ring.

Fig. E is a top view similar to Fig. B, but illustrating the attachment of the annuloplasty ring to the mitral valve annulus.

Fig. F is a top view of the mitral valve illustrating an Alfieri stitch technique for reducing the gap between the posterior and anterior leaflets.

Fig. G is a top view of the mitral valve illustrating another suturing technique which has been used to close the gap between the posterior and anterior leaflets.

Fig. H is a cross sectional view of the heart anatomy illustrating the coronary sinus (CS) running behind the posterior leaflet of the mitral valve.

Fig. I is a cross sectional view of the heart anatomy similar to Fig. H, but illustrating a technique for inserting anchors into the CS using a catheter based system.

Fig. 1A is a cross sectional view of the heart anatomy similar to Fig. I but illustrating an improved catheter based procedure for inserting anchors into the CS and correcting for mitral valve insufficiency according to the invention.

Fig. 1B is an enlarged view of the connector placed in accordance with the invention through the CS and the annulus tissue of the mitral valve.

Fig. 2A is a cross sectional view of the mitral valve illustrating the posterior and anterior leaflets and the relative position of the CS with respect to the valve annulus.

Fig. 2B is a view similar to Fig. 2A and illustrating the effect of cinching or pulling the CS toward the mitral valve opening at a location which is above the level of the valve annulus.

Fig. 2C is a view similar to Fig. 2B, but illustrating the placement of a fastener in accordance with the invention to bring the level of the CS closer to the annulus before cinching.

Fig. 3 is a cross sectional view of the heart anatomy, on the left side of the heart, illustrating a catheter based system according to the invention.

Figs. 3A-3D illustrate a progression of steps in a catheter based method for correcting a mitral valve insufficiency in accordance with the invention.

Figs. 4 and 5 illustrate a cross section of the mitral valve in which anchors have been daisy chained together and then cinched to close the gap between the leaflets of the valve.

Figs. 6A-6E-1 illustrate a cross section of the heart anatomy through the CS and illustrating a pair of catheter devices being used to successively apply fasteners in a daisy chained fashion and both cinch and lock the fasteners in place.

Figs. 6F and 6F-1 illustrate the final locked positions of the fasteners, flexible tensile member and locking member placed via catheters.

Figs. 7A-7F are enlarged cross sectional views of the mitral valve at the valve annulus taken generally along line 7-7 of Fig. 6A and showing the placement of a fastener from the CS downwardly through the valve annulus to the underside or left ventricle side of the valve.

Figs. 8A and 8B illustrate cross sectional views, respectively, through the CS and illustrating the use of a pair of magnets in the CS for magnetically guiding and locking up with a magnet on an anchor delivery catheter.

Fig. 8C is an enlarged view of the various magnets and their magnetic fields.

Fig. 9 is a cross sectional view of the heart anatomy through the CS, and illustrating the use of electromagnets in a catheter device.

Fig. 10 is a cross sectional view of the heart anatomy through the CS and illustrating the successive positioning of a catheter device relative to another catheter device in the CS through the use of magnets.

Figs. 11A and 11B illustrate cross sectional views of the heart anatomy through the CS and respectively illustrating nonactivated and activated positions of a series of magnetic fasteners used for correcting a mitral valve insufficiency.

Figs. 11A-1 and 11B-1 respectively illustrate enlarged views of the magnetic fastener system in its nonactivated and activated states.

Fig. 11C is a cross sectional view through the mitral valve and CS illustrating the final activated position of the fastener system placed in accordance with Figs. 11A and 11B.

Figs. 12A and 12B illustrate an alternative in which the magnetic fasteners are placed respectively in the CS and in the left atrium.

Figs. 13A and 13B are cross sections of the heart anatomy through the CS and illustrating an additional magnetic fastener placed below the annulus in left ventricle to assist with reducing the mitral valve insufficiency.

Figs. 14A and 14B are cross sections through the CS and mitral valve and illustrating another alternative magnetic fastening system.

Fig. 14C is similar to Fig. 14B, but illustrates a magnetic fastener with additional mechanical fastening elements in the form of projections which engage and penetrate tissue proximate the valve annulus.

Figs. 14D and 14E are perspective views illustrating the magnetic fastening elements with mechanical tissue engaging projections.

Figs. 15A-15C are cross sections through the CS and mitral valve illustrating an alternative fastener delivery mechanism in which a fastener is delivered through a catheter and also through magnetic guiding elements.

Figs. 15D and 15E are cross sections similar to Fig. 15A, but illustrating a series of fasteners delivered through magnetic guiding elements and daisy chained together using a flexible tensile member.

Figs. 16A-16C are cross sectional views similar to Figs. 15A-15C, but illustrating the use of magnetic guiding elements which have separable portions.

Figs. 16A-1 and 16A-2 are perspective views of the magnetic guiding elements respectively shown in nonseparated and separated positions.

Figs. 16D and 16E are similar to Figs. 15D and 15E, and illustrate the daisy chained connection of the fasteners with the magnetic guiding elements removed.

Fig. 17 is a perspective view showing a fastener delivery mechanism on a catheter which includes a magnetic guiding element magnetically coupled to a second magnetic guiding element of a second catheter.

Figs. 18A-18C respectively illustrate cross sectional views of the heart anatomy through the CS and the mitral valve and the placement of an alternative catheter delivered fastening system.

Fig. 19A is a cross sectional view of the heart anatomy through the CS and the placement of another alternative catheter delivered fastening system.

Figs. 19B and 19C illustrate the daisy chained fasteners of Fig. 19A respectively before and after cinching of the fasteners to shorten the valve annulus.

Figs. 20A and 20B illustrate a cross sectional view of tissue receiving fasteners formed from shape memory alloy both before and after activation of the shape memory effect to shorten the overall length of the tissue engaged with the fasteners.

Fig. 21A is a cross sectional view of the heart anatomy through the CS and illustrating the use of a catheter to delivery a series of fasteners in the form of tissue penetrating fasteners separated by pledgets along a flexible tensile member.

Figs. 21B-21D respectively illustrate enlarged views of the fastener delivery system shown in Fig. 21A as well as the final cinching thereof.

Fig. 22 illustrates an alternative system to Figs. 21A-21D in which a secondary cinching mechanism is provided in the form of a second flexible tensile member.

Figs. 23A-23E illustrate respective cross sections of the heart anatomy through the CS and the use of another alternative catheter based system for serially delivering fasteners coupled with a flexible tensile member used to cinch valve tissue and correct a mitral valve insufficiency.

Figs. 24A-24C are respective cross sections through the heart anatomy including the CS above the mitral valve and illustrating another alternative catheter based fastener system.

Figs. 25A-25D illustrate an enlarged cross section of the catheter based system of Figs. 24A-24C, and showing the cinching and locking thereof.

Figs. 26A-26B illustrate another alternative cinching and locking system for a catheter based fastener system similar to Figs. 25A-25D.

Figs. 27A-27B illustrate yet another alternative cinching and locking mechanism associated with a catheter based fastener system similar to Figs. 26A and 26B.

Figs. 28A and 28B are respective cross sections similar to Figs. 27A and 27B, but illustrating another alternative fastening system.

Figs. 29A-B illustrate respective cross sections of yet another catheter based fastening system.

Figs. 29C-D illustrate respective cross sections of yet another catheter based fastening system.

Fig. 30 illustrates a cross section of yet another catheter based fastener system.

Figs. 30A and 30B are cross sections of another catheter based fastener system.

Fig. 30C is a cross section of another catheter based fastener system.

Fig. 31A is a cross section taken along line 31A-31A of Fig. 30.

Fig. 31B is a cross section taken along line 31B-31B of Fig. 30.

Figs. 32A and 32B illustrate another alternative fastening system in its nonactivated and activated states.

Fig. 32C is a cross section taken along line 32C-32C of Fig. 32A.

Fig. 33 is a cross section of another alternative fastening system.

Figs. 33A and 33B are enlarged cross sectional views of portions of Fig. 33 respectively shown in nonactivated and activated states.

Figs. 34A-34I are respective cross sections of the heart anatomy successively showing the use of another alternative catheter based fastening system.

Fig. 35A is a cross section taken through the CS and illustrating a perspective view of another alternative catheter based fastener delivery device.

Figs. 35B-35E are respective cross sections of the fastener delivery device shown in Fig. 35A and used to deliver multiple fasteners coupled to a flexible tensile member.

Fig. 35F is a cross sectional view of the fastening system delivered, cinched and locked to shorten the length of tissue engaged with the system.

Fig. 36 is a perspective view of the distal end of another alternative catheter based fastener delivery system.

Fig. 37A is a fragmented view of the distal end of another catheter based system for delivering a fastener and valve support member of the invention.

Figs. 37B and 37C respectively illustrate the deployed valve support and fastener system on the mitral valve.

Figs. 38A-38I respectively illustrate cross sections of the mitral valve and CS and the progression of using another catheter based fastener delivery system.

Figs. 39A and 39B respectively illustrate cross sections of the distal end of a crimping and cutting device which may be used with various catheter based systems of this invention.

Figs. 40A-40D respectively illustrate cross sections through the heart anatomy including the mitral valve and CS, and illustrating another alternative catheter based fastener delivery system.

Figs. 41A-41C illustrate another catheter based fastener delivery system.

Fig. 42A illustrates an elevational view of one exemplary fastener usable in the systems described herein.

Fig. 42B is a cross sectional view taken along line 42B-42B of Fig. 42A.

Fig. 43 is a side elevational view of another alternative fastener having a curved shape.

Figs. 44A-44C respectively illustrate the use of another alternative fastener suitable for the systems of the present invention.

Figs. 45A and 45B are schematic drawings illustrating the use of an alternative surgical tool for delivering anchors and flexible tensile members with a surgical approach.

Fig. 46A is a perspective view of a tool similar to the tool shown in Figs. 45A and 45B, but illustrating multiple arms at the distal end.

Fig. 46B is a perspective view of the distal end of the tool shown in Fig. 46A, illustrating the arms in an expanded condition.

Fig. 47A is a perspective view of another anchor/flexible tensile member delivery device delivering three anchors to the annulus of the mitral valve from a position within the LV.

Fig. 47B is a perspective view of the system shown in Fig. 47A illustrating the deployment of an alternative locking device.

Figs. 47C-47F are respective cross sectional views illustrating use of the device shown in Figs. 47A and 47B to plicate and lock a series of anchors and flexible tensile members together.

Fig. 47G is a cross sectional view taken along line 47G-47G of Fig. 47E.

Fig. 47H is a view similar to Fig. 47G, but illustrating the full deployment of the locking device onto the sutures.

Figs. 48A and 48B are cross sectional views of an alternative locking device illustrated respectively in an unlocked and locked position relative to a pair of sutures.

Detailed Description

In this description of illustrative examples, like reference numerals refer to like element throughout the drawings. Like reference numerals with prime (') marks, double prime ('') marks, or triple prime (''') marks refer to like structure except for minor differences which will be apparent. Figs. 1A and 1B illustrate an improved catheter delivered fastener system 50' which involves placing a permanent fastener or anchor 60 from the CS 46 through the wall of the left atrium 12 proximate annulus 40 for anchoring purposes. This improvement may be applied to the prior cinching method illustrated in Fig. I discussed above. The fastener 60 may be deployed and anchored in various manners, including those discussed further below. Because the fastener 60 extends not only through the delicate CS tissue, but also through the thicker tissue of the left atrium 12, secured anchoring takes place and, upon cinching using a flexible tensile member 54, the annulus 40 may be reduced to correct for a prolapsed valve or other mitral valve insufficiency with less risk of tearing tissue. Figs. 2A and 2B illustrate the anatomical relationship between the CS 46 and the mitral annulus 40. In particular, the CS 46 can be noncoplanar with the mitral annulus 40, causing CS based cinching approaches to the inefficient to effectively modify the shape of the annulus 40. In many cases, the CS 46 extends above the mitral annulus 40 along the left atrial wall and, instead of pulling the annulus 40 toward the valve opening or gap 32, the left atrial wall is instead pulled inwardly as shown in Fig. 2B. This causes more of a restriction of the atrium 12 above the valve 20, rather than a reduction of the annulus 40 itself and, therefore, prevents a complete correction of the valve insufficiency in this case. In an approach which is similar to the approach shown in Figs. 1A and 1B, but having additional benefits, a fastener or

anchor 62 extends from the CS 46 into the left ventricle side of the annulus 40. This plicates the tissue between the CS 46 and the left ventricle 14 thereby bringing the CS 46 closer to and/or more in line with the annulus 40. Once this plication has taken place as shown in Fig. 2C, a CS cinching device can more efficiently and effectively reduce the mitral annulus 40. That is, when cinched toward the valve opening or gap 32, the cinching device, which is more in line with the valve annulus 40, can better pull the posterior leaflet 24 toward the anterior leaflet 22 thereby closing the gap 32 between the leaflets.

As shown in Figs. 3, 3A and 3B, a pair of magnetically attractive catheters 64, 66 can be used in concert with each other using the CS 46 as an approximate guide to locate and position the tip of another catheter or catheter portion at the mitral annulus 40. More specifically, as one example, one catheter 66 includes both a magnetic guiding portion 66a and an anchor delivery portion 66b positioned in a predetermined manner, such as at a predetermined acute angle relative to the magnetic portion 66a. Another catheter 64 is placed in the CS 46 and includes a magnetic guiding portion 64a. The two magnetic guiding portions 64a, 66a magnetically couple with one another to lock up the position of the anchor delivery catheter portion 66b at a predetermined angle which will properly deliver a fastener or anchor 68 into a desired portion of the tissue. As shown in Fig. 3A, the magnetically locked catheters 64, 66 can deliver a first loop type anchor or fastener 68 through the valve annulus 40 on a skewed or otherwise known trajectory from the axis of magnetic attraction, such that the loop type anchor or fastener 68 is accurately placed, for example, through the annulus 40 from the left ventricle side to the left atrium side of the mitral valve 20. As shown in Fig. 3B, the CS catheter 64 can be translated to a different position within the CS 46 causing the magnetic tip 66a of the left ventricle catheter 66 to follow along the annulus 40 where subsequent loop type anchors or fasteners 68 may be placed in a similar fashion to the first applied anchor or fastener 68. Fig. 3C illustrates that a loop type fastener or anchor 68 may capture a T-bar type anchor or fastener 70 passing from the CS 46 through the left atrial wall using a catheter delivery system 72 guided within the CS 46. In this embodiment, fasteners 68 are therefore placed from the left ventricle 14 into the left atrium 12, and additional connecting fasteners 70 are placed from the CS 46 into the left atrium 12 for engagement with the other fasteners 68. As shown in Fig. 3D, multiple loop and T-bar anchors or fasteners 68, 70 may be cinched together with a flexible tensile member 74 similar to a drawstring-type configuration, resulting in

alignment of the CS 46 and the annulus 40 into a more coplanar relationship at several locations. The cinching or drawstring action therefore closes the gap 32 between the posterior leaflet 24 and the anterior leaflet 22 in a more even and effective manner.

Fig. 4 illustrates magnetically attractive catheter portions 64a, 66a respectively in the CS 46 and under the mitral annulus 40 used to deliver a series of anchors or fasteners 76 with a T-bar shape from the left ventricle side of the mitral valve 20 to the left atrium side of the mitral valve 20. As also shown in Fig. 4, the T-bar shaped anchor fasteners 76 are delivered in a daisy chained fashion from catheter portion 66b such that a second catheter 78 may be used to cinch a drawstring or flexible tensile member 80 to shorten or reduce the valve annulus 40. As shown in Fig. 5, the anchors or fasteners 76 may be cinched together using the drawstring or flexible tensile member 80 within catheter 78 to pull the posterior leaflet 24 toward the anterior leaflet 22. The flexible tensile member 80 is then locked in place or otherwise secured to retain the fasteners 76 in their new positions, such as in one of the manners described below.

Figs. 6A-6F respectively illustrate catheters 82, 84 being placed into the heart 10 through the aortic valve into the left ventricle 14 and through the CS 46 generally adjacent the valve annulus 40. This top view of the heart 10 shows how a first T-bar type anchor or fastener 86 having a tail, forming a flexible tensile member 88, is loaded into the CS catheter 84 at the proximal end 84a so that it may be pushed down to the distal tip 84b to be in position for delivery. The position of the left ventrical catheter 82 with a magnetic tip 82a is also shown generally opposite to the distal tip 84b of the CS catheter 84. As shown in Fig. 6B, a second anchor or fastener 90 is delivered in a daisy chain fashion by running an eyelet 90a on the second anchor 90 over the tail or flexible tensile member 88 associated with the first anchor 86. Fig. 6C illustrates the second anchor 90 of the daisy chain delivered through the valve annulus 40 at a spaced apart location from the first anchor 86. Fig. 6D illustrates a third anchor 92 at the annulus 40 similarly delivered along flexible tensile member 88 using an eyelet portion 92a. Anchor 92 is threaded through the CS catheter 84 and driven through the tissue generally at the valve annulus 40. In the case of this type of anchor, respective transverse bar portions 86b, 90b, 92b of the anchors or fasteners extend into the left ventricle 14. Fig. 6E illustrates a locking member 94, including a crimp 96 delivered over the daisy chain tail or flexible tensile member 88 within the proximal CS 46. Locking member 94 is shaped or otherwise configured to hold its position

within the CS 46. Fig. 6E-1 illustrates the crimp 96 before crimping onto the flexible tensile member or tail 88. As shown in Figs. 6F and 6F-1 a catheter device 98, which may be deployed through a suitable delivery catheter (not shown) may be used to pull the flexible tensile member 88 thereby cinching the assembly and pulling the posterior leaflet 24 toward to the anterior leaflet 22. Once this cinching is accomplished, the crimp is crimped against the flexible tensile member 88 adjacent to the lock member 94 to keep the assembly at the desired position.

Fig. 7A illustrates how magnetically attractive portions 82a, 84b of the LV and CS catheters 82, 84 should be strongly attracted when the gap distance (d_1) is relatively short. If this gap distance d_1 is not relatively short, then other methods of increasing the lock up force may be necessary as further described herein below.

Figs. 7B and 7C illustrate how a T-bar type anchor or fastener 86 would be pushed from an opening 84c in the CS catheter through the tissue from the CS 46 into the left ventricle 14 until it is fully deployed across the tissue. Fig. 7D illustrates a larger gap d_2, through which two magnetic portions 82a, 84b of the respective LV and CS catheters may magnetically couple, depending on the magnetic attractive forces developed. In Figs. 7E and 7F, the magnetic catheter in the LV 14 has not been illustrated (only for purposes of clarity), such that the delivery of a T-bar type fastener or anchor 86 may be shown in its fully deployed state across the tissue. As shown in Fig. 7F, the T-bar portion or transverse portion 86b of the fastener 86 self-rotates in order to fit snugly along the annulus 40 under the posterior leaflet 24. In Fig. 7G, the relative position of the CS 46 to the annulus 40 is improved after cinching of the anchor 86 plicates the tissue between the annulus 40 and the CS 46 as previously described.

Figs. 8A-8C illustrate that multiple magnets 102a, 102b may be used in the CS, such as on a CS catheter 102, to attract an opposite magnet pole at the tip 100a of the LV catheter 100. This allows the LV catheter 100 to be steered in three axes to deliver a fastener through a second catheter portion 100b into the annulus 40. It will be appreciated that multiple magnets may also or alternatively be used in the LV 14 and/or in the LA for steering purposes and/or additional magnetic force. Fig. 8C illustrates in detail how a pair of magnets 102a, 102b in the CS 46 mounted such that like poles are facing each other results in a 360° magnetic field which attracts the opposite pole of a magnetic

catheter tip 100a within the LV 14. This can eliminate the need to rotationally orient the CS catheter 102 so that its pole is facing an opposite pole in the LV 14.

Fig. 9 illustrates the use of electromagnets 104 in a CS catheter 106 which may be used in conjunction with or as replacements for permanent magnets as described in the above embodiments. It will also be appreciated that one element which generates magnetic forces may be used in conjunction with another element which is magnetically attracted to the magnetic force generating element, but not necessarily a magnetic force generating element itself. For example, an electromagnet or permanent magnet may be positioned on one side of the tissue to be anchored, and another element formed from ferrous metal may be positioned on the opposite side of the tissue for magnetic coupling purposes while a fastener or anchor is driven into the tissue.

Fig. 10 illustrates a CS catheter 108 configured with multiple opposite pole magnetic pairs 110, 112 along its length and a steerable LV catheter that may be directed to each discrete pair of magnets 110, 112 to delivery anchors or fasteners (not shown), such as in one of the manners previously described.

Now referring to Figs. 11A, 11A-1, 11B and 11B-1, a CS catheter 116 may be configured with multiple discrete magnets 118 along its length, wherein the poles of the magnets 118 are arranged such that they are magnetically attracted to each other, yet kept apart by a restraining force, such as pressurized air directed to a bladder-like structure 120 between the magnets 118. In this case, the magnets 118 are being used as fasteners to fasten or trap tissue therebetween. A similar catheter 122 delivers magnets 124 on an opposite side of the tissue, such as within the LV 14. When the restraining force is removed, such as by reducing the air pressure as shown in Figs. 11B and 11B-1, the magnets 118 are attracted to each other and thereby modify the valve annulus 40 such that the posterior leaflet 24 is pulled toward the anterior leaflet 22. As shown best in Figs. 11B and 11C, each strip of magnets 118, 124 has opposing poles along its length and thereby plicates the tissue by removing a restraining force between the magnets 118 in the CS 46, thereby allowing the attracted magnets 118 to move toward each other and plicate the annulus tissue therebetween. The magnets 124 in the LV catheter 122 may be configured in the same manner as magnets 118.

Figs. 12A and 12B illustrate respective strips of magnets 118, 124, as described in connection with Figs. 11A-11C in the CS 46 and the LA 12

instead of the LV 14. The two strips of respective magnets 118, 124 align with each other such that the magnets 118, 124 are anchored to each other across the left atrial wall. In this case, once again, the stronger atrial wall is used as the anchoring tissue, as opposed to the CS tissue only. When the magnets 118 in the CS 46 are brought together, as discussed above, an annular reduction of the mitral annulus 40 is achieved similar to the manner discussed above.

Figs. 13A and 13B illustrate strips of magnets 118, 124 in the CS 46 and LA 12 as discussed previously. However, cinching via the CS 46 alone may not have sufficiently precise pull on the mitral annulus 40 since these two anatomical structures typically do not lie at the same level. Even the two strips of magnets 118, 124 shown in Fig. 12B are only coupled across the left atrial wall, and this may not be in line with the annulus 40 at all locations. Therefore, an additional magnet 126 shown in Figs. 13A and 13B, fixed to a metal or otherwise substantially rigid curved bar 128, is placed under the mitral valve 20 in the LV 14, such that magnet 126 locks up with the strip of magnets 118 in the CS 46. This pulls the exterior annulus 40 toward the CS 46 and establishes a more coplanar relationship.

Fig. 14A illustrates a modification of the strip of magnets 124 positioned in the LA 12 such that there is an extension magnet 130 which is positioned at the midpoint of the strip of magnets 124. This extension magnet 130 extends down to the mitral valve annulus 40 bridging the gap between the CS 46 and the valve annulus 40. This may pull a magnet 132 and curved support bar 134 under the valve 20 tighter to the CS 46, as shown in Fig. 14B. It will be appreciated that magnet 132 and support bar 134 are similar to magnet 126 and support bar 128, except that bar 134 has a fabric covering 136 as may be desired for tissue ingrowth purposes. Figs. 14C-14E illustrate the use of additional mechanical fasteners such as projections 138 on one or more of the magnets 132 used in the embodiments described above. This can apply additional traction or fastening to the tissue than could otherwise be supplied by the use of magnets alone.

Figs. 15A-15E comprise a series of illustrations showing another alternative catheter based fastener delivery system. In addition to showing the use of a fastener 140 to pull the CS 46 into a more coplanar relationship with the annulus 40 (Fig. 15C), this system utilizes magnets 142, 144 which have orifices 142a, 144a through which the fastener 140 is delivered such that more precise placement of the fastener 140 may be obtained in certain instances while also

using a magnetic lock up force for more positively driving the anchor or fastener 140. It will be appreciated that magnet 144 will be coupled to a catheter (not shown) for positioning within the CS 46. Magnet 142 may be releasably coupled to a steerable catheter 146. As shown in Figs. 15D and 15E, after a plurality of magnets 142, 144 and fasteners 140 have been delivered such that tissue is trapped therebetween, a flexible tensile member 148 and crimps 150 may be used to cinch and lock the fasteners 140 together thereby pulling the posterior leaflet 24 toward the anterior leaflet 22 and closing a gap 32 in the valve 20.

Figs. 16A-16E, as well as Figs. 16A-1 and 16A-2 illustrate a system which is the same as the system shown in Figs. 15A-15E, except that the magnets 142', 144' are formed of separable portions, such as halves 142a, 142b, 144a, 144b, so that the magnets 142', 144' may be removed after the fasteners 140' have been properly delivered. Thus, the anchors or fasteners 140' themselves have portions 140a, 140b which retain the fasteners 140' in place across the tissue proximate the annulus 40, and portions 140b accept a flexible tensile member 148 and crimps 150 for cinching and locking purposes as shown in Figs. 16D and 16E generally in the manner or manners described herein. The separable magnet portions 142a, 142b and 144a, 144b may be coupled to suitable catheter devices allowing their release from fasteners 140' and withdrawal from the patient.

Fig. 17A illustrates an alternative fastener delivery system 160 using magnetic guidance in which the fastener 140' is not delivered through the magnets 162, 164, but is delivered adjacent to the magnets 162, 164 in a fastener driving portion 166 of a catheter 168. This is another manner of using magnetic guidance and temporary lock up without the necessity of leaving the magnets 162, 164 in place after completion of the procedure.

Figs. 18A-18C illustrate a more conventional annuloplasty that may be accomplished using magnetic guidance and lock up in a temporary manner to facilitate fastener placement and driving. More specifically, a magnetic strip 170 is placed into the CS 46 using a catheter 172. A second magnetic strip 174 with a fabric covering 176 is placed in the left atrium 12 also via a catheter 178. Fasteners 180 are placed into the fabric 176 on the strip 174 in the left atrium 12 from the undersurface of the mitral valve 20 again using a catheter 82. Likewise, fasteners 180 are driven through the CS 46 and left atrium wall into the fabric 176 in a manner similar to that described with respect to, for example, Fig. 3C and 3D through a catheter with a sideward firing fastener driving portion (see also

Figs. 7D-7F). The magnetic strips 170, 174 are removed from the fabric covering 176 and from the CS 46 and the fabric 176 is then drawstringed or cinched with a suitable flexible tensile member 184 coupled therewith to produce annuloplasty or pulling of the posterior leaflet 24 toward the anterior leaflet 22 to eliminate or reduce a gap 32 in the mitral valve 20.

Figs. 19A-19C illustrate one alternative to a T-bar configuration of fasteners as previously described. In this embodiment, fasteners 190 in the form of anchor buttons 190a are placed below the mitral valve 20 along the annulus 40 using catheters 192, 194 with magnetic guidance and lock up as previously described. Although not shown, another catheter is used in the left atrium to deliver buttons 190b which couple with buttons 190a. Buttons 190a are further coupled to a flexible tensile member 196 which may be secured with crimps 200 (one shown in Fig. 19C) as previously described. This compresses the mitral tissue between respective tissue engaging portions of the buttons 190a, 190b. The buttons 190a, 190b are drawstringed or cinched from below using flexible tensile member 196 threaded through respective eyelet portions 198 of each button 190a.

Figs. 20A and 20B illustrate another way to plicate the annulus 40 by using memory alloy staples 202 driven into the tissue along the annulus 40. When the memory alloy activates, the staples 202 shorten and plicate the tissue (Fig. 208) to shorten the annulus 40 of the mitral valve 20 to pull the posterior leaflet toward the anterior leaflet as generally described above.

Figs. 21A-21D illustrate the placement of fasteners 210 on the left atrial side of the mitral valve 20, daisy chained to pledgets or fasteners 212 in the form of tissue trapping load spreading members underneath the annulus 40. These fasteners 210, 212 are coupled together by a flexible tensile member 214 or drawstring, in this case. Figs. 21A-21C illustrate a catheter 216 which delivers fasteners 210, 212 in a serial fashion along flexible tensile member 214 such that fasteners 210 are driven through the tissue and fasteners or pledgets 212 are released between each fastener 210. The series of fasteners 210, 212 is then drawn together using the drawstring or flexible tensile member 214 as shown in Fig. 21D. This shortens the distance between each of the fasteners 210, 212 and the entire structure with elements above and below the annulus 40. The tissue becomes trapped between the fasteners 210, 212 spreading loads over larger areas and reducing tear out risks.

Fig. 22 illustrates a modified version of the system illustrated in Figs. 21A-21D. In this embodiment, after the first drawstring 214 is pulled to tighten the various fasteners 210, 212' and plicate the annulus 40 as generally shown in Fig. 21D, a second drawstring 218 coupled to eyelets 220 each of the pledgets 212' may be pulled for a secondary shortening operation which further reduces the annulus 40, as necessary.

Figs. 23A-23E illustrate an alternative embodiment which is similar to Figs. 21A-21D, except that the pledgets 212'' have a pair of holes 222, 224 through which the flexible tensile member 214 or drawstring is threaded, as opposed to an eyelet structure.

Figs. 24A-24C illustrate another embodiment of a catheter based fastener system 230 which employs a series of connected magnets 232, 234 with one series of magnets 232 lying in the CS 46 adjacent to the mitral valve annulus 40 and another series 234 lying in the LV 14 adjacent to the annulus 40. The magnets 232 residing in the CS 46 are coupled together by coil springs 236 and by a flexible tensile member 238, while the magnets 234 in the LV 14 are, in one embodiment, positioned individually in the LV adjacent to magnets in the CS 232, after release from the LV magnet delivery catheter 240, as shown in Fig. 24C. In another embodiment, the array of LV magnets 234 is shown in Fig. 24A adjacent to the CS magnets 232 and connected by a member consisting of a sheath 233 upon which the magnets 234 can slide. The array of magnets 234 and the sheath 233 are deposited in the LV 14 as the delivery catheter 240 is withdrawn. The connecting sheath 233 prevents the risk of an embolic accident resulting from a detachment of a single magnet 234. In Fig. 24B, the withdrawal of the LV delivery catheter 240 is shown in more detail. The most distal magnet 234 is shown attached to the sheath 233, whereas the next more proximal magnet 234 is still on the shaft of the delivery catheter 240. Each series of magnets 232, 234 is introduced into the positions shown in Figs. 24A-24C by respective catheters 242, 240. A coupling 244 is provided and is releasably coupled to a pull wire or cable 246 in the catheter 242 such that the series of magnets 232 may be cinched or drawn together to reduce the circumferential length of the valve annulus 40. The LV magnets 234, owing to their attraction to their CS counterparts 232, are thus pulled together to accomplish plication of the dorsal cusp of the mitral valve 20 adjacent to the annulus 40. Plication may be better facilitated by features on the surface of the CS magnets 232 that grip the endocardial surface, and promote ultimate tissue ingrowth about the magnets 232

to strengthen the plication. Once the proper reduction has taken place, the magnets 232 are locked in place, and the catheter 242 is removed. If the plication is not adequate or is not acceptable for some reason, the magnets 232 may be re-expanded and re-positioned as desired prior to locking. There may be a tactile detent associated with a user control (not shown) to indicate a fully cinched condition. Other embodiments described herein may also have re-expansion capability. Fig. 24C illustrates the coil springs 236 fully compressed and the valve leaflets 22, 24 brought together in proper coaptation. It will be appreciated that springs 236 may require various degrees of compression depending on the amount of valve re-shaping that is necessary. Also, the valve annulus may be plicated such that the tissue at or near the annulus is folded or otherwise compressed.

Referring more specifically to Figs. 25A-25D, the operation of the coupling 244, and a release and locking mechanism 250 is shown. The initial position is shown in Fig. 25A in which the magnets 232 are spaced apart by the uncompressed coil springs 236 and the flexible tensile member 238 which is fixed to a coupling element 252 having at least a pair of arms 254, 256 which releasably grip a complimentary coupling element 258. The complimentary coupling element 258 is fixed to a pull wire or cable 260 extending within the delivery catheter 242. The wire or cable 260 is pulled as shown in Fig. 25B to compress the coil springs 236 and reduce the distance between each adjacent pair of magnets 232, thereby reducing the circumferential length of the annulus 40 (Fig. 24C) as the magnets 234 within the LV 14 passively follow the magnets 232 in the CS 46. At this point, the delivery catheter 242 may be pushed to the left as viewed in Figs. 25B and 25C causing a crimping action of a tube 262 affixed to the most proximal magnet 232. A crimped portion 262a is then retained within a recessed portion of the coupling element 252. At the same time, the gripping arms 254, 256 release the complimentary coupling element 258 of the pull wire or cable 260 and the delivery catheter 242 and pull wire or cable 260 may then be removed leaving the locked fastener system 230 in place as shown in Fig. 25D.

Figs. 26A and 26B illustrate a fastener system 270 which operates the same as that disclosed in Figs. 24A-24C and 25A-25D, except that an accordion or bellows type section 272 replaces each coil spring 236, and internally and externally threaded coupling elements 274, 276 replace the gripping arms 254, 256 and coupling element 258. It will be appreciated that the operation of the system shown in Figs. 26A and 26B is the same as that described in the previous embodiment, except that releasing the coupling element 276 will involve

rotating the pull wire or cable 260 to decouple the threaded coupling elements 274, 276. The recessed portion 252a of coupling element 252 can have an essentially square cross section. The crimped portion 262a of tube 262 will thus engage the recessed portion and plastically deform about it to prevent rotation of coupling element 252 with respect to threaded coupling element 276. The coupling element 276 and cable can thus be effectively unthreaded and released.

Figs. 27A and 27B illustrate another alternative catheter based fastener system 280 which is the same as those described with respect to the two previous embodiments, except that the coil springs 236 and accordion shaped bellows sections 272 have been replaced by respective telescoping portions 282, 284 which carry the magnets 232 fixed therein. When the telescoping portions 282, 284 are drawn together, the smaller diameter sections 282 are retained in the shortened position by a locking mechanism operating on the flexible tensile member 238, such as previously described, thereby maintaining the shortened configuration of the system. Also, a releasable coupling 286 is formed by a quarter turn bayonet type fastener as opposed to the gripping arms 254, 256 and element 258, or the threaded connection 274, 276 of the two previous embodiments. In the present embodiment, an elastomeric pad 252b is seated distal to the proximal component of the bayonet connector 286. When the bayonet 286 is engaged in the delivery position, the pad 252b creates a load on the proximal component which prevents inadvertent release of the system 280. The recessed segment 252a of the coupling element can have a square cross section to prevent rotation of the coupling during disengagement of the bayonet, in a manner similar to the previous embodiment. The telescoping portions 282, 284 are flexible and also pivot so that they can conform to the curved shape of the CS 46. When the pull wire or cable 260 is pulled to the right as illustrated in Figs. 27A and 27B, the telescoping portions 282, 284 can move together such that detents 288 move from one recess 290 to an adjacent recess 292 of the respective telescoping portions. The assembly is then locked in place as previously described and the bayonet coupling 286 is released for purposes of withdrawing the delivery catheter 242.

Figs. 28A and 28B are illustrative of another embodiment which is the same as the system shown in Figs. 27A and 27B, except that the telescoping portions 282', 284' are fabricated of a flexible, elastomeric polymer material to allow the fastener system 280' to conform to the curve of the CS 46 (Fig. 24C). This is to be contrasted with the fastener system 280 shown in Figs. 27A and

27B, in which the telescoping elements 284 are fabricated of a relatively more rigid material. In this previous embodiment, flexibility is gained primarily from the length of the detents 290 and 292, which allow angled positioning of one telescoping element relative to an adjacent one. In the current embodiment, additional flexibility of the fastener is achieved with the length of the detents 290 and 292. In the embodiments of Figs. 27A-B and 28A-B, a separate locking mechanism may not be necessary but would provide an added measure of protection against inadvertent re-expansion.

Figs. 29A-B and 29C-D illustrate respective alternative embodiments of systems 280'' and 280''' using telescoping members containing magnets similar to the previous embodiment. Previous embodiments included systems of telescoping members with detents for both the fully extended position and the fully shortened or cinched configurations. The two embodiments shown in Figs. 29A-D employ a single detent for only the fully extended position. Figs. 29A-B illustrate an implant 280'' especially suitable for use in the LV. Implant 280'' may be delivered by a catheter 298 upon which the system will be loaded. The catheter 298 will occupy a position analogous to that occupied by the central tensile member 238 in the CS implant 280''' shown in Figs. 29C-D. Such a catheter 298 can have an outer diameter which is expandable to frictionally retain the individual telescoping elements 232. This type of mechanism is described below with respect to Figs. 30, 31A, and 31B. The LV implant 280'' is delivered so that the magnets 232 register with the magnets 232 of the CS implant 280'' in their fully separated positions. The catheter 298 is then withdrawn. When the CS implant 280''' (Figs. 29C-D) is fully shortened or cinched using tensile member 238, the LV magnetic elements 232 (Figs. 29A-B) are passively driven towards one another to plicate the mitral valve tissue between the individual elements 232. Release of the cinched CS implant 280''' may be achieved by one of the three release mechanisms previously described, or by another method, after the implant 280''' has been cinched or shortened.

Like reference numbers in Figs. 29A-D refer to like structural elements, while like reference numbers with one or more prime marks refer to corresponding elements between embodiments that have been somewhat modified as will be apparent. More specifically, Figs. 29A-D illustrate systems 280'', 280''' which are similar to those described in the previous embodiment, except that the telescoping portions 282'', 284'' only have one recess location 290' for initially retaining the relative positions of the telescoping portions 282'', 284'' as

shown in Figs. 29A and 29C. The telescoping portions 282'', 284'' are fabricated from a flexible polymer capable of plastic deformation to allow portion 282'' to pass beyond 290' and enable collapse of the system to the fully shortened configuration. Also, telescoping portions 284'' of LV implant 280'' may have projections 296, as shown in Figs. 29A-B which act as mechanical fasteners for engaging tissue within the LV 14. As illustrated in Figs. 29C-D, the telescoping portions 284''' of the CS implant 280''' can have an uninterrupted smooth surface, thereby preventing trauma to the intimal surface of the CS.

Figs. 30, 31A and 31B illustrate another catheter based system 300 for placing magnets adjacent the mitral annulus, such as within the LV 14 (Fig. A). In this system, a delivery catheter 304 receives a plurality of annular magnets 306. Magnets 306, for example, may have roughened outer surfaces 306a for tissue engagement purposes. The catheter 304 has an outer diameter which is expandable to frictionally retain the magnets 306 at spaced apart locations. An internal tube 308 may be withdrawn, to the left as illustrated in Fig. 30, to release the magnets 306 from their frictional engagement with the outer surface of the delivery catheter 304. As one example, a steerable delivery catheter 304 is shown with a manipulator wire 310 for deflecting the curve of the distal segment 312 of the catheter 304, and also a core wire 314 to confer column strength and torquing capability to the delivery catheter 304. Once the magnets 306 are magnetically coupled to additional magnets (not shown) across the annulus tissue, for example, the internal tube 308 may be withdrawn thereby releasing the delivery catheter 304 from magnets 306 and facilitating its withdrawal. The magnets may be joined by a tubular sheath 316 upon which the magnets 306 may or may not slide. For example, the sheath 316 may be positioned, and its inside diameter sized, such that it slides freely on the delivery catheter when the internal tube 308 is withdrawn. The internal tube 308 could frictionally lock both the sheath 316 and magnetic fasteners 306 when it is deployed in its fully distal position.

Figs. 30A and 30B are longitudinal cross sections similar to Fig. 30, but illustrating an alternative system 300' for delivering respective magnets 307a-e within the CS and adjacent to the annulus tissue 40. In this embodiment, however, a sleeve 316' occupies a space on the outside of catheter 304 and within the inner diameter of the annular magnets 307a-e. The most distal magnet 307a is fixed to sleeve 316', while the remaining magnets 307b-e may slide along the sleeve 316' after magnets 307b-e have been released through the action of

internal tube 308 as described in connection with Fig. 30. Magnets 307b-e may be selectively and serially delivered by release from sleeve 316'. Cinching may be accomplished by pulling the most distal magnet 307a proximally toward the adjacent magnet 307b thereby creating plicated tissue 309 proximate the annulus 40 as the tissue is trapped between respective magnets 307a, 307b and magnets 306, for example, within the LV. The process may be repeated with the more proximal magnets 307c-e, and a like number of magnets 306 until the annulus tissue is plicated into a desired condition.

Fig. 30C illustrates another longitudinal cross section of an alternative system 300'. This system is similar to the systems shown in Figs. 30, 30A and 30B, except that a sleeve 316'' is utilized on the outer diameter of a distal magnet 306 and respective proximal magnets 306'. Distal magnet 306 may be fixed to sleeve 316'', while magnets 306' may slide relative to sleeve 316''. In other respects, system 300'' operates the same as described in connection with Figs. 30A and 30B with magnets 306 and 306' being selectively and serially released at the proper position and subsequent cinching taking place between magnet 306 and adjacent magnet 306', as well as between magnets 306' by way of a proximal pulling or cinching of distal magnet 306.

Figs. 32A-32C illustrate another catheter based system of fasteners comprising a series of magnets 320a-d held for sliding movement along parallel wires 322, 324, 326, and 328. In this embodiment, the system is delivered to the CS 46 adjacent to the region of mitral valve cusp to be plicated to reduce size of the mitral annulus. The system may be delivered in a manner similar to the embodiment described in Fig. 24C. Cinching this system drives the movement of magnets (not shown) placed in the LV 14 adjacent to magnets 320a-d to accomplish plication of the valve cusp between the LV magnets. For example, magnets 306 of the embodiment illustrated in Fig. 30, may be placed adjacent to magnets 320a-d with tissue located therebetween. A suitable mechanism (not shown), is provided for pulling the magnets 320a-d together along wires 322, 324, 326, and 328 to produced a fully cinched configuration, as illustrated in Fig. 32B. The fully cinched configuration is achieved by pulling the most distal magnet 320a towards the most proximal magnet 320d by pulling all four wires 322, 324, 326, 328 proximally. A flexible tensile member (not shown) can connect the four wires to a coupling element similar to coupling element 252 in Fig. 25A. Locking in the configuration illustrated in Fig. 32B may be achieved by a mechanism similar to that of the embodiments described in Figs. 25, 26, and 27. The series of

magnets 320a-d is locked in the position shown in Fig. 32B, for example. In this embodiment, magnets 320a-d are coated with a soft polymer 321 which frictionally engages small stop members 322a, 324a on wires 322, 324 to assist with retaining desired positions of the magnets 320b-d during delivery of the series of magnets 320b-d into position prior to cinching.

Figs. 33, 33A and 33B illustrate another system of fasteners placed via a delivery catheter 242 and including a coupling mechanism 244 and locking mechanism 250 as described above in connection with Figs. 25A-25D. This system may be delivered to the CS 46 to drive movement of magnets (not shown) placed in the LV to accomplish plication of the mitral valve as described in the previous embodiments. This system is similar to that described in Figs. 26A and 26B in that bellows or crumple zones 330 are provided between magnets 232, as best illustrated in Figs. 33A and 33B to accommodate movement of adjacent magnets 232 together as they slide along the flexible tensile member 238 while flexible tensile member 238, which is rigidly attached to the most distal magnet 232, is pulled to the left as viewed in Fig. 33. The operation of this embodiment is otherwise the same as that described in connection with Figs. 26A and 26B.

Figs. 34A-34I comprise a series of illustrations of a catheter based system for applying a series of fasteners through tissue generally at the mitral valve annulus and using guidance magnets 102a' , 102b' and 100a' (as previously described) in the CS 46 and the LV 14. In this embodiment, a left ventrical catheter 340 has a portion 342 which uses radio frequency (RF) to effectively drill an initial hole through the tissue and then insert a second larger diameter catheter portion 344 which is steerable, for example, as shown in Figs. 34B-34D, to make a second hole in the annulus tissue 40. It will be appreciated that the various catheters disclosed herein may have distal portions which are steerable in various manners for accurate positioning purposes. In this embodiment, tip 344 is movable into a desired hook-like position by a guiding cable 344a which may be pulled to configure tip 344 into the hooked shape as shown. The catheters utilized herein can include unidirectional or bi-directional steering. A steering mechanism may be positioned within and/or on the devices. Typically, the steering mechanism may include a pull wire 344a terminating at a flat spring or collar. The steering system has a more flexible distal section compared to the proximal catheter tube body. When tension is placed on the pull wire 344a, the catheter distal end 344 is deflected into a curve, which helps direct the device within a heart chamber, for example. The pull wire 344a may be

wound, crimped, spot welded or soldered to the flat spring or collar (not shown) placed in the catheter end 344. This provides a stable point within the device for the pull wire 344a to exert tensile force and thus steer the device. The more proximal portion of the catheter may be reinforced by incorporating a helically wound or braided wire therein to provide column support from which to better deflect the distal section 344. Alternatively, the steering mechanism may consist of a superelastic material having a desired three-dimensional geometric shape at its distal end and sufficient rigidity to impart this shape in the device. By retracting the preformed steering wire into the stiffer proximal section of the device, the distal end of the device straightens. Extending the preformed steering wire into the more flexible distal section of the device causes the distal section to assume the shape of the steering wire. Alternatively, a device with a curved section can incorporate a tube or rod that can be advanced through that section to straighten it. An additional feature that may be incorporated in the device is a preformed shape in the distal section of the device. The distal section may be preformed into a curve that biases the device to maximize tissue contact when the device is positioned into the appropriate heart chamber. This curve may consist of a single arc or a nonlinear geometry, such as an "S". A pre-shaped rod, hypotube, wire or coil, created from a memory elastic material such as nickel titanium or spring steel may be thermally formed into the desired geometry, and inserted into the distal section (including a separate lumen) of the device during manufacturing or advanced through a dedicated lumen while the device is positioned in the heart. The shaped wire may be attached to the distal tip of the device for those non-removable pre-shaped rods and secured to the handle of the device at its proximal end to provide a reinforcing structure throughout the entire length of the device. The device body may also or alternatively be thermally formed into a desired geometry.

As shown in Fig. 34A, the various systems of this invention may also include different manners of ensuring that the catheter device(s) is/are properly position adjacent to tissue prior to use. For example, an impedance measurement device 343 may be coupled to the perforating element itself, such as RF wire 342, or electrodes on the perforating element or on any separate element carried by the system. Such proximity determining devices may be used to confirm contact between the catheter device and the tissue surface by comparing the impedance between the electrode (such as RF wire 342) and a return path (indifferent patch electrode or second element electrode). When the

electrode(s) only contact blood, the impedance is substantially higher than when the electrode element is in contact with the tissue surface. Each electrode is connected to a signal wire, with the signal wire connected to impedance measurement device 343. The signal wire may be connected to the impedance measurement device 343 by way of a connector and cable system. The measurement device 343 may be a power supply, a simple electrical resistance meter, or any other suitable device and method of use.

As further illustrated in Fig. 34C, a balloon portion 346 of the left ventricle catheter 340 may be inflated to stabilize the catheter 340 against the tissue 40 as the holes are being formed. As shown in Fig. 34E and 34F, a fastener 348 is delivered through the lumen of the steerable catheter portion 344 and is coupled with a flexible tensile member 350 and another fastener 352. The first and second fasteners 348, 352 are deployed on the same side of the tissue 40 at spaced apart locations with the flexible tensile member 350 coupled therebetween. These fasteners 348, 352 may be formed essentially as torsion spring members which may have a portion which captures and locks against the flexible tensile member 350 in the deployed position as shown in Fig. 34F. Once the first fastener 348 is deployed as shown in Fig. 34G, the flexible tensile member 350 may be pulled to plicate the tissue 40 between the first fastener 348 and the steerable catheter portion 344. At this time, the second fastener 352 is delivered and captures and locks with the flexible tensile member 350 to lock the length of the flexible tensile member 350 between the two fasteners 348, 350 with the tissue plicated as shown in Fig. 34H. This process may be repeated, as necessary, to plicate additional annulus tissue 40 for further annulus reduction.

Figs. 35A-35F illustrate another catheter device 360 for delivering multiple fasteners 362 attached with a flexible tensile member 364, for example, in the LV 14 at the annulus 40. As best shown in Fig. 35B, the catheter device 360 includes three fastener delivery portions 366, 368, 370. One portion 368 is a central portion at the distal end of the catheter device 360 and deploys a first fastener 362. Two additional fastener delivery portions 366, 370 are spaced on opposite sides of the central portion 368 and preferably may be actively moved to preferred positions relative to central portion 368 to deliver additional fasteners 362. A flexible tensile member 364 couples each fastener 362 together as well as to a plurality of pledgets or tissue support members 372. A fastener drive mechanism 374 is used to drive one or more of the fasteners 362 through the tissue and comprises a reciprocating rod 376 which is activated by spring force

developed in a coil spring 378. When a pair of magnets 380, 382 are decoupled by pulling a wire or cable 384, for example, the spring forces the reciprocating rod 376 upwardly as viewed in Fig. 35B to drive the fastener 362 through the tissue 40. It will be appreciated that similar mechanisms may be used with flexible drive rods 386, 388 in driving the outer fasteners 362 through the tissue, or this same mechanism 374 may be coupled with flexible drive rods 386, 388 to simultaneously drive each of the fasteners 362 through the tissue 40. All three fasteners 362 are thereby deployed, in addition to the pledgets 372, as illustrated in Fig. 35E. Then, the drawstring or flexible tensile member 364 are pulled tight to plicate the tissue 40 as shown in Fig. 35F and a crimp member 390 is applied to lock the flexible tensile member 364 in the tensioned position to retain the plicated tissue 40 in the desired state.

Fig. 36 illustrates an alternative embodiment of the catheter device 360 shown in Fig. 35A-35F, in which the distal end of the catheter device 360' includes a magnet 400 for locking up temporarily with one or more magnets (not shown) in the CS 46 (Fig. A) as previously described. This allows the catheter device 360' to be accurately positioned and temporarily locked in place proximate the annulus 40 while the anchors or fasteners 362 are being delivered, cinched and locked in place as previously described with respect to Figs. 35A-35F.

Figs. 37A-37C illustrate another alternative catheter delivery device or system 410, and valve support/fastener system 412 for plicating annulus tissue 40 and pulling a posterior leaflet 24 toward an anterior leaflet 22. In this embodiment, a C-shaped support member 414 is initially retained within a catheter 416 in a nonactivated, compact state as shown in Fig. 37A. When the support member 414 is pushed from the distal end of the catheter 416, it springs into a deployed or activated state as shown in Figs. 37B and 37C. The anchors or fasteners 418 are retained on the rod shaped support member 414 for sliding movement and are coupled together by one or more flexible tensile members 420. An additional flexible tensile member 422 extends from another catheter portion 424 and provides for secondary cinching or drawstring action. A magnet 426 is rigidly coupled to a central fastener or anchor 418 at P2, as shown, or otherwise coupled to the support rod 414 and temporarily locks up with a magnet 428 in the CS 46 generally as previously described. Fasteners or anchors 418 are then connected to the annulus tissue 40 such as by using additional fastening elements (not shown) which are delivered via another catheter (not shown) within the LV 14, in one of the manner previously described. Once the anchors or fasteners 418

are secured to the tissue 40, the flexible tensile members 420 are pulled thereby pulling each of the fasteners or anchors 418 toward one another along the support member 414. A final or secondary pulling action may be obtained by pulling the flexible tensile member ends 422 extending into the catheter portion 424 extending from the main catheter 416. Various manners may be used to retain the flexible tensile members 420, 422 and anchors 418 at the new positions shown in Fig. 37C, such as by using crimp members (not shown), or integrated ratchet-type or frictional engagement structure (not shown) which automatically locks the flexible tensile members 420, 422 in place as they are pulled.

Figs. 38A-38I illustrate another catheter based system and method for delivering, for example, three fasteners or anchors coupled to respective flexible tensile members and cinched together to reduce a mitral valve annulus 40. In this embodiment, as shown in Fig. 38A, a CS catheter 430 and LV catheter 432 may temporarily lock up through magnetic coupling and an initial hole may be formed through the annulus tissue 40 using RF energy applied via a wire 434. A first fastener or anchor 436 coupled with a flexible tensile member 438 may be deployed through the hole using a catheter 440 threaded over a guide tube 442. The catheter 440 may be removed and another catheter 444 having bifurcated portions 444a, 444b may be used by threading one of the bifurcated portions 444a over the flexible tensile member 438. Alternatively, once the first fastener 436 and flexible tensile member 438 are deployed as shown in Fig. 38F, the second portion 444b of the catheter 440 may be activated and moved to a spaced apart location to form a hole using an RF wire 434 and then deploy a second fastener 446 and flexible tensile member 448 (Fig. 38H). Then, the first catheter portion 444a and second catheter portion 444b are removed and the first catheter portion 444a is threaded along the second flexible tensile member 448. A third anchor 450 and attached flexible tensile member 452 are then deployed from the second catheter portion 444b resulting in three deployed anchors 436, 446, 450 and flexible tensile members 438, 448, 452 as shown in Fig. 38H. A crimping and cutting device 460 is then used to pull the flexible tensile members 438, 448, 452 and fasteners or anchors 436, 446, 450 together to thereby pull the posterior leaflet 24 toward the anterior leaflet 22 and then a crimp member 462 is applied to the flexible tensile members 438, 448, 452 and cut to result in the system being fastened generally as shown in Fig. 38I. As alternatives to RF energy, other manners and devices may be used for forming a hole through tissue prior to or while inserting an anchor or fastener. For example, these may include needles,

blades, coring devices, etc. which can effectively create a starter hole in the tissue such that less force is required to drive an anchor into or through the tissue.

As shown in Figs. 39A and 39B, the crimping and cutting device 460 includes a crimping portion 470 comprising jaws 472a, 472b with projections 472 for applying force to the crimp member 462 and a cutting portion 474 coupled with an RF energy source 476. After the crimping portion 470 is actuated to crimp the crimp member 462 onto the flexible tensile members 438, 448, 452, the RF energy source 476 is activated to cut the flexible tensile members 438, 448, 452 as shown in Fig. 39B using cutting element a 477. To facilitate crimping, one threaded portion 478 of the device is rotated with respect to another portion 479. This pulls jaws 472a, 472b proximally to bring them together against the crimp member 462.

Fig. 40A illustrates the use of an additional magnet 480 in the left atrium 12 for supplying additional magnetic force at the junction of the annulus 40 and CS 46. An arrangement of magnets 480, 482, 484 may be used for temporarily locking up the catheter system at the location that it is desired to deliver a fastener or anchor (not shown), such as in those manners previously described. Figs. 40B-40D illustrate an alternative fastener delivery system and method for delivering fasteners 486 in the left atrium 12 as opposed to the left ventricle 14 as previously described. This system is otherwise similar in that magnetic guidance and lock up first temporarily occurs between the various magnets 480, 482, 484 in the system. Once this magnetic lock up has taken place, a fastener 486 and flexible tensile member 488 may be delivered through a steerable portion 490a of a catheter 490 in the left atrium 12 such that the fastener 486 is delivered into the left ventricle 14. Steering mechanisms, such as those described elsewhere herein may be used to accurately direct catheter portion 490a. A number of fasteners 486 and attached flexible tensile member or members 488 may be deployed as shown in Fig. 40D and then cinched or drawn together using a crimping and cutting device 460 as previously described.

Figs. 41A-41C illustrate another embodiment of a catheter delivered fastening system. In this embodiment, it will be understood that a series of fasteners 500, 502, 504 and attached flexible tensile members 506, 508, 510 may be delivered as previously described and as shown in Figs. 41A and 41B. A delivery catheter 520 may include a balloon 522 for stabilizing against the tissue 40 and/or for positioning respective arms 520a, 520b, 520c of the catheter device 520 while delivering the anchors or fasteners 500, 502, 504 and each of their

attached flexible tensile members 506, 508, 510. A valve support member 530 may then be delivered through a catheter (not shown) as shown in Fig. 41B. The support member 530 has eyelets 532, 534, 536 which are threaded over each of the respective flexible tensile members 506, 508, 510. Respective crimps 538, 540 are applied to the outer eyelets 532, 536 and the flexible tensile members 506, 510 cut proximate to each crimp member 538, 540. The central flexible tensile member 508 is pulled to thereby pull the posterior leaflet 24 at P2 toward the anterior leaflet 22. When suitable tension and pulling action has taken place, a third crimp member 542 is applied proximate the central eyelet 534 at the apex of the V-shaped and the flexible tensile member 508 is cut proximate to the crimp member 542. This results in approximation of the posterior and anterior leaflets 22, 24 as shown in Fig. 41C.

Figs. 42A and 42B illustrate one possible anchor or fastener 550 usable with the various systems of the present invention. Such an anchor 550 may be rigidly coupled to a flexible tensile member 552, or coupled such that the anchor or fastener 550 slides along the flexible tensile member 552, as necessitated by the fastening system in which the fastener 550 is being used.

Fig. 43 is a side elevational view of an alternative fastener 560 which is similar to that shown in Figs. 42A and 42B, except that the fastener 560 has a curved outer profile. The convex surface 562 of the curved outer profile is adapted to engage tissue and cause less trauma to the tissue than the flat profile shown in Figs. 42A and 42B.

Figs. 44A-44C illustrate another alternative fastener 570 useful in the various systems and methods of this invention. This fastener 570 includes two radially expandable portions 572, 574 which may be delivered through a catheter 576 in their nonexpanded state shown in Fig. 44A, and then expanded on opposite sides of the tissue 40 to be trapped therebetween, as shown in Figs. 44B and 44C.

Referring now to Figs. 45A and 45B, a tool 600 can have anchors and tethers or flexible tensile members (not shown) pre-loaded within so that they can be applied in sequential fashion to the LV side of the annulus 40 of mitral valve 20 from a surgical incision in the LV wall 602. As a surgical tool, rather than a percutaneous catheter, the size of the device 600 can be capable of accommodating all of the features required, including multiple anchors and tethers, a locking member such as a crimp or other element(s), and a cutting tool for severing the flexible tensile member. Cinching, locking and cutting could all be

accomplished with or through this same tool 600. The handle 604 of the device 600, in addition to embodying the mechanism to deploy anchors via a squeeze member 606 could also have various other control features necessary for operation.

In addition to the tethered anchors, this tool could allow other approaches requiring compression force, such as clips and staples, either as anchors or as plication elements directly, because of the shorter shaft length, the possibility to be stiffer than a catheter, and the mechanical advantage that could be achieved by an ergonomic trigger-style handle. Further, the possibility having a larger shaft size would also make incorporation of delivery of an annuloplasty ring to the LV side of the annulus be more easily accomplished than by a percutaneous catheter.

The tool 600 could be adaptable in shape, or come in a kit of several shape options, to allow perpendicular orientation of the tool 600 toward the annulus regardless of the location of the incision through the LV wall. For example, if a Dor incision was located more basal on the heart (versus apical), the tool 600 might require an angle of at least 45 degrees in order to facilitate access to the annulus 40.

In addition to a tool 600 that might deliver a single anchor to a single position of the tip of the tool at the annulus 40, a tool 610 as shown in Figs. 46A and 46B may be configured and operated similar to the catheter versions shown and described in Figs. 35A through 36, or for two anchor deployment, Figs. 38F and 38G. Such a surgical tool would be highly beneficial, again because of its shorter length, stiffer shaft, and better opportunity to control the deployment and the positioning of the lateral arms 612, 614 at the correct location at the annulus 40 for anchor delivery. Either by direct visualization, or with aid of a fiberoptic scope, the procedure could be accomplished through only a small incision in the LV apex as an elective surgical technique, allowing mitral annuloplasty surgery to be performed in a minimally invasive manner, through a mid-thoracotomy or even a port-access endoscopic procedure. The scope could be delivered through the same annuloplasty tool, or separately through an additional incision in the LV wall, or separately but through the same incision as the surgical annuloplasty tool is delivered.

The tools and procedures described in connection with Figs. 45A-B and 46A-B may especially benefit certain patients who present following a transmural anterior wall myocardial infarct with an akinetic or dyskinetic wall

segment. These patients have been shown to benefit from endoventricular circular patch plasty as described by Dor. Reconstructive surgery of the altered left ventricular topography results in a permanent improvement in the ventricular wall function, including non-ischemic zones remote from the anterior wall left ventricular aneurysm. These patients also often have concomitant mitral valve dilation that results in significant regurgitation. A tool, such as tools 600, 610 that could be used at this time that could allow quick and easy performance of a mitral annuloplasty, as an alternative to attempting a traditional surgical implantation of an annuloplasty ring, would be highly beneficial. It will be understood that other features of the various embodiments and methods of percutaneous catheters previously described for performing mitral annuloplasty may be incorporated into a tool specifically advantageous for this adapted surgical approach.

Referring now to Figs. 47A-47H, catheter 618 is shown with another alternative flexible tensile member lock device. This may also be applied to other catheter based systems or surgical tool implementations. In order to lock multiple anchors 620 and flexible tensile members 622 together to hold a cinched plication, the tensile members 622 must be held respective to each other after the procedure is completed. One common way to do this is to tie a knot. Pushing a knot down two such sutures is well known and involves starting the knot proximally and pushed until it rests against the target, be it a blood vessel or such. Pushing knots by catheter is also known, however, this could be problematic if more than two sutures (flexible tensile members) are involved because of possible entanglement and premature knotting (that is, a knot stopping before it reaches its intended distal location).

The feature shown in Figs. 47A-H is a self-locking device in which the device 624 is held open as the sutures 622 are manipulated through it, but when ready to lock, the device 624 is deployed in a way that causes it to self-collapse down onto the sutures 622 thereby locking them in place. In this case, force is applied to maintain the device 624 open, rather than applied to cause it to close. Specific designs might include a tapered inner diameter collet, a wound spring, a braid, or other design that would self collapse when released from the open position. Further, it is contemplated that such a device could be fixed in the loaded configuration at the tip of a catheter specifically intended to perform cinching as well as locking, and also optionally cutting of the excess suture length proximal to the fixation point. A cinch/lock/cut catheter could be advanced over

all individual sutures 622 allowing them to be axially moved relative to each other but once the desired relative positions are achieved to cause the desired annuloplasty, the self-collapsing locking device 624 would be released such that it clamps down onto the sutures 622 holding all sutures 622 and attached anchors 620 in position.

For example, a coil 624 could be loaded on the end of a cinching catheter 630. When coil 624 is pushed off of the tip of the catheter 630 by another catheter or tube 632, it collapses down onto the sutures 622 thereby locking sutures 622 into the cinched position as shown in stepwise fashion in Figs. 47C-47F. As further shown in the cross sections of Figs. 47G and 47H, device 624 may have an associated cutting portion 624a that cuts the sutures at the proximal end of the device 624 as the lock is fully deployed (Fig. 47H).

Figs. 48A-B illustrate respective unlocked and locked conditions of another device 640 for securing one or more sutures or flexible tensile members 622 into place. In this embodiment the sutures 622 are free to travel in one direction, but will not travel in the opposite direction. The device 640 includes a hard ball 642 inside a body 644. As shown in Figure 48A, the free pull direction for sutures 622 is downward, while the locking direction is upward.

The locker body 644 has a shallow inner draft (taper). When the sutures 622 are pulled upward, the sutures 622 are wedged between the hard ball 644 and the tapered inner surface 644a. The harder the sutures are pulled, the more the ball 642 is wedged against the sutures, and the harder the sutures 622 are wedged against the tapered body 644.

When the sutures 622 are pulled in the opposite direction, the ball 642 is drawn away from the tapered surface 644a, and the sutures are free to travel. The sutures can be locked and unlocked repeatedly, simply by reversing the direction of pull. The body 644 may be metal or relatively hard plastic, such as PEEK. The ball may be metal, or ceramic, such as Alumina, Sapphire, or Ruby.

After the ball 642 is placed inside the body 644, the lower end may be crimped (Fig. 48B) simply to prevent the ball 642 from exiting the body 644. The crimped section of the body 644 stops the ball from exiting the body 644, yet will not wedge the sutures 622 between the ball 642 and the body 644 with enough force to prevent the sutures 622 from moving in the free-travel direction. This feature may be a steep wall that results from the crimp process, or may be a ring or other stop that is inserted into the body 644.

Locking device 640 can serve the primary purpose of locking multiple sutures or flexible tensile members to one another while under load and enabling such a function from a remote location via the device(s) discussed herein for delivery of anchors and sutures or other flexible tensile members. The intended utility of this system is primarily for use in percutaneous surgical procedures, however, it may be used during more invasive surgical procedures or any other procedure utilizing sutures either internal or external to the body. The function of device 640 is desirable as the development of many otherwise percutaneous procedures have been hindered due to insufficient means to fixate sutures in tension over long periods of time due to the inherent flaws of manually tying sutures or the limited abilities of knot tying devices.

Alternatives

In addition to various other disclosure in this regard hereinabove, various aspects of the invention may be practiced in alternative forms. Thus, the description contained below is directed to non-limiting examples of such alternative aspects.

I. Target Tissue Locators can include:
   a. Anatomical Structures (as a guide)
   b. Visualization / Sensors
   c. Reference Markers
   d. Combinations of a,b,c

II. Target Tissue Locating Methods (fixed and or removable) can include:
   a. Visualization
      i. Angiography
      ii. 2D (IVUS) or 3D (Biosense Webster, Endocardial Solutions, Etc.) Ultrasound
      iii. Fiber optic
      iv. Fluoroscopic markers
      v. Intravascular Ultrasound (IVUS)
      vi. MRI
   b. Tissue Contact Confirmation
      i. Catheter shape (for example, the distal end of catheter will deflect when in contact with atrial wall, valve annulus or other tissue structure)
      ii. Doppler sensor

iii. Electrical impedance

iv. Guide wire unable to be advanced past the distal end of a device (deployment / guiding, etc)

v. Pressure sensor (contact)

vi. Pressure sensor (flow)

vii. Ultrasonic transducer

c. Location Reference

i. Markers

1. Fluoroscopic

a. Contained within the device material (Barium Sulfate, bismuth trioxide, etc.)

b. Separate component (such as a radiopaque band, etc.) – the marker may also be used as an electrode (to confirm tissue contact by electrical impedance)

2. Ultrasonic

ii. Multiple device reference / alignment

1. Electrical impedance (between the two devices)

2. Markers (complete or partial circumference – partial circumference makers would allow alignment confirmation)

3. Perforator and snare devices

III. System Devices can include:

a. Deployment Device

i. Single or multiple devices,

ii. Single or multilumen,

iii. Steerable or guidewire for positioning,

iv. Proximal thumb slide with stylet for advancement of implant.

b. Guiding Device (guiding catheter or introducer, for example)

i. Straight, curved (including coiled to fit on the valve annulus) or steerable (to direct the deployment device to the target location).

c. Separate Device(s)

i. At least one device for target tissue location,

ii. At least one device for implant deployment,

iii. At least one device to evaluate the effectiveness of treatment, during the procedure (if desired),

iv. At least one of the above device utilities may be incorporated onto (or in) one or more devices.

IV. Fastener / Anchors can include:

a. For use with a tether / flexible tensile element, or just the anchor (to displace tissue around the annulus, moving the leaflets closer together)

b. Protrusions or other structure or material to resist movement once implanted

i. Barb,

ii. Coil,

c. Self expanding

i. Shape memory or superelastic material (polymer, metal, or metal alloy),

ii. Swellable material

1. The fastener / anchor devices or other inserts may be partially (coated, for example) or completely fabricated from materials that swell, or expand when they are exposed to a fluid, such as blood. These biocompatible materials include, but are not limited to, hydrophilic gels (hydrogels), regenerated cellulose, polyethylene vinyl acetate (PEVA), as well as composites and combinations thereof and combinations of other biocompatible swellable or expandable materials.

2. The fastener / anchor or other inserts may not have to be made using a swellable material to achieve the desired effect. They should displace tissue once inserted into (partially, or completely through) the valve annulus, while not creating a leak path from the ventricle. Further, the non swellable implantable devices may include at least one self expandable region, such as used on a molly bolt, to displace annular tissue inward (using NiTi implant, for example). These implants do not necessarily have to be round – they may be oval, the insertion edge may have a rectangular shape matching the geometry of the valve annulus or any other suitable shape.

V. Tether / Flexible Tensile Member Assembly can:

a. Be deployed on the anterior, posterior, and/or sides of the valve.

b. Include at least one tethered fastener / anchor

i. Tether may be movable or locked onto anchor.

ii. Tether may include an elastic or non-elastic material

1. Manual plication – use locking element for tether,

2. Automatic plication – elastic tether with fixed distal and proximal anchor components, such as:

a. Suture, wire, rod, band, ribbon, combination or other suitable element,

b. Shape memory or superelastic material (polymer, metal, or metal alloy).

VI. Locking Elements may include:

a. Adhesive Assisted Bonding

i. Inside crimped elements

ii. On suture (at location desired to be bonded together)

b. Clip, Staple

c. Coil

i. Straight

ii. Tapered cone shaped

iii. Tightly wound

iv. Spaced windings

v. Suture through coil ID

vi. Suture through at least one coil wind

d. Figure 8 Wire Hoop

e. Heat Fusing

i. RF, DC

ii. Ultrasonic

f. Knot

i. Similar to the method utilized by surgeons during suturing of an annuloplasty ring or replacement valve.

g. Rings / Collars

i. Interference fit

ii. Crimped

h. Tapered Cone (non-coil)

i. Interference fit

ii. Crimped

i. Tube

i. Single

ii. Multiple

iii. Tapered end

iv. "L" Shaped

v. Crimped

VII. Excess Tether / Flexible Tensile Member Severing Methods (post locking procedure) can include:

a. A feature to allow the cutting device to be guided to the locking element over the excess suture. Also, it may be desirable to have a space from the distal tip to the severing element, to prevent the excess suture from being cut too close to the locking element.

i. Blade Cutting Methods

1. Guillotine / shearing cutter
2. Rotating cutting halves
3. Scissor type

ii. Heat Cutting Methods

1. RF, DC
2. Ultrasonic
3. Other

iii. Other Severing Methods

1. Twisting

VIII. Coatings

a. At least one implanted element or assembly may include a coating to:

i. Assist healing,

1. The fastening / anchor devices (and or any other system element such as the lockers, tether / flexible tensile member, etc) may include one or more agent(s) that may be incorporated into the structure forming the device and/or incorporated into a coating. Such therapeutic agents may include, but are not limited to, antithrombotics (such as anticoagulants), antimitogens, antimitotoxins, antisense oligonucleotides, gene therapy solutions, nitric oxide, and growth factors and inhibitors. Direct thrombin inhibitors that may be beneficial include Hirudin, Hirugen, Hirulog, PPACK (D-phenylalanyl-L-propyl-L-arginine chloromethyl ketone), Argatreban, and D-FPRCH.sub.2 Cl (D-phenylalanyl-L-propyl-L-arginyl chloromethyl ketone); indirect thrombin inhibitors include Heparin and Warfarin (coumadin). Alternatively, a clot promoter may be used, such as protamine sulphate or calcium hydroxide. Additional therapeutic materials include aspirin, dexamethasone, dexamethasone phosphate, streptokinase, tocopherol, TPA, urokinase, paclitaxel (Taxol), actinomycin, rapamyacin, or other. Sirolimus, or other antibiotics may also be used. The therapeutic compounds/solutions may be blended with the device base materials during fabrication, applied just prior to

deployment, or after the device has been deployed. Additionally, the therapeutic materials may be located on, through, inside, or combination of the device in holes, grooves, slots or other indentation to allow elution of the therapeutic compound(s). Post device fabrication coating methods include, but are not limited to, dipping, spraying, brushing, submerging the devices into a beaker containing a therapeutic solution while inside a vacuum chamber to permeate the device material, etc.

ii. Increase bond between implant to tissue

1. The bonding materials could be in the form of a liquid, semi-solid, or solid. Suitable bonding materials include gels, foams and micro-porous meshes. Suitable adhesives include acrylates, epoxies, fibrin-based adhesives, UV light activated adhesives and/or heat activated adhesives and other specialized adhesives. The adhesive can be selected to bond on initial contact, or after a longer period to allow repositioning if desired. One effective adhesive is a crystalline polymer that changes from a non-tacky crystalline state to an adhesive gel state when the temperature is raised from room temperature to body temperature. Such material is available under the trade name Intillemer™ adhesive, available from Landec Corp. Composites and combinations of these materials also can be used.

iii. Displace tissue to increase the effectiveness of treatment

1. Hydrophilic gels (hydrogels), foams, gelatins, regenerated cellulose, polyethylene vinyl acetate (PEVA), as well as composites and combinations thereof and combinations of other biocompatible swellable or expandable materials.

IX. Miscellaneous

a. Additional Versions and Methods of Use

i. The valve repair devices and accessories described herein (with or without modifications) can also be used during cardiopulmonary supported, beating heart, stopped heart, open field, closed-chest, minimally invasive, port, endoscopic, laparoscopic and or robotically assisted surgery, combination and or other cardiovascular technique. The devices described herein may include a hand-held device used through a median sternotomy, lateral thoracotomy, intercostals, port-access, mini-sternotomies, other less invasive approaches involving subxiphoid access, inguinal approaches, or sub-thoracic approaches adjacent the diaphragm.

While the present invention has been illustrated by a description of various preferred embodiments and while these embodiments has been described in some detail, it is not the intention of the Applicant to restrict or in any way limit the scope of the appended claims to such detail. Additional advantages and modifications will readily appear to those skilled in the art. The various features of the invention may be used alone or in any combination depending on the needs and preferences of the user. This has been a description of the present invention, along with the preferred methods of practicing the present invention as currently known.

What is claimed is:

1. A method of reducing regurgitation of blood through a heart valve having annulus, the annulus positioned apart from a coronary sinus at least at one location, comprising:

fastening the coronary sinus to the annulus to bring the annulus closer to the coronary sinus at least at the one location, and

modifying the annulus so as to reduce regurgitation of blood through the heart valve.

2. The method of claim 1, wherein fastening the coronary sinus further comprises:

inserting a first guide element into the coronary sinus,

directing a second guide element adjacent to the annulus,

securing the first and second guide elements together, and

applying a fastener between the annulus and the coronary sinus.

3. The method of claim 2, wherein securing the first and second guide elements together further comprises temporarily magnetically attracting the first and second guide elements together while applying the fastener.

4. The method of claim 2, further comprising:

using the same catheter device to direct the second guide element and apply the fastener.

5. The method of claim 1, further comprising:

applying a second fastener to the annulus,

coupling the first and second fasteners together, and

reducing the distance between the first and second fasteners to shorten the circumferential length of the annulus.

6. The method of claim 5, further comprising:

applying the first and second fasteners through the same catheter device.

7. The method of claim 6, further comprising:

serially applying the first and second fasteners through one lumen in a catheter device.

8. The method of claim 6, further comprising:

applying the first and second fasteners through different lumens of the same catheter device.

9. The method of claim 5, wherein at least one flexible tensile member is used to couple the first and second fasteners together and reducing the distance between the first and second fasteners further comprises applying tension to the flexible tensile member.

10. The method of claim 1, wherein modifying the annulus further comprises:

fastening a flexible fabric to the annulus and shortening the circumferential length of the flexible fabric.

11. The method of claim 1, wherein modifying the annulus further comprises:

connecting at least two fasteners to the coronary sinus at spaced apart locations,

coupling a flexible tensile member to the two fasteners, and

tensioning the flexible tensile member to reduce the distance between the two fasteners.

12. The method of claim 1, wherein the coronary sinus lies above the annulus at least at the one location and fastening the coronary sinus to the annulus further comprises moving the coronary sinus downward to a position more adjacent to the annulus at least at the one location.

13. A method of modifying the spatial relationship between a coronary sinus and an annulus of a heart valve, the coronary sinus lying at least partially apart from the annulus at least at one location, comprising:

applying a fastener through the annulus and into the coronary sinus, and

using at least the applied fastener to bring the coronary sinus closer to the annulus at least at the one location.

14. The method of claim 13, wherein using at least the applied fastener to bring the coronary sinus closer to the annulus further comprises:

moving the coronary sinus downwardly to a position adjacent the annulus at least at the one location.

15. The method of claim 13, further comprising:

temporarily anchoring the coronary sinus to the annulus at least at the one location while applying the fastener.

16. The method of claim 15, wherein temporarily anchoring the coronary sinus to the annulus further comprises moving the coronary sinus and annulus together with magnetic elements at least at the one location.

17. A method of modifying an annulus of a heart valve to reduce regurgitation of blood through the valve, comprising:

delivering a first fastener through a catheter into the coronary sinus,

delivering a second fastener through a catheter to at least one of two locations, the two locations being: 1) generally above the annulus in the left atrium, and 2) generally below the annulus in the left ventricle,

securing the first and second fasteners to the annulus, and

reducing the distance between the first and second fasteners thereby reducing the circumferential length of the annulus.

18. The method of claim 17, wherein the second the fastener is delivered to a location above the annulus in the left atrium of the heart.

19. The method of claim 17, wherein the second fastener is delivered to a location below the annulus in the left ventricle of the heart.

20. The method of claim 17, further comprising:

connecting a flexible tensile member between the first and second fasteners, and

shortening the distance between the first and second fasteners to modify the annulus.

21. The method of claim 20, further comprising:

locking the flexible tensile member into position with respect to the fasteners by applying a crimp member to the flexible tensile member through a catheter.

22. The method of claim 17, further comprising:

holding the first and second fasteners in spaced apart positions while securing the first and second fasteners to heart tissue at the two locations, and

biasing the first and second fasteners toward each other to reduce the distance between the first and fasteners.

23. The method of claim 22, wherein biasing the first and second fasteners further comprises:

magnetically attracting the first and second fasteners in a direction toward one another.

24. The method of claim 23, wherein biasing the fasteners further comprises:

spring biasing at least one of the first and second fasteners in a direction toward the other.

25. The method of claim 22, wherein pressurized air is used to hold the first and second fasteners in the spaced apart positions.

26. The method of claim 17, further comprising:

using radio frequency energy to form an aperture in the heart tissue in order to deliver the first and second fasteners to the two locations.

27. A method of modifying an annulus of a heart valve to reduce regurgitation of blood through the valve, comprising:

delivering respective magnets through at least one catheter to at least two of three locations adjacent the annulus, the three locations being 1) within the coronary sinus, 2) generally above the annulus in the left atrium, and 3) generally below the annulus in the left ventricle,

magnetically coupling the delivered magnets to trap tissue therebetween, and

reducing the circumferential length of the annulus with the respectively delivered magnets.

28. The method of claim 27, further comprising:

delivering a plurality of spaced apart magnets into each of the two positions, and

modifying the annulus by reducing the distance between the spaced apart magnets.

29. The method of claim 27, wherein at least one of the magnets delivered to each location further includes a mechanical fastening element configured to penetrate tissue, and the method further comprises:

driving the fastening elements into the tissue at each location to secure the magnets to the tissue.

30. A method of applying a fastener to an annulus of a heart valve, comprising:

placing a first magnet in a coronary sinus using a first catheter,

placing a second magnet adjacent the annulus, outside of the coronary sinus, using a second catheter,

magnetically coupling the first and second magnets, and

applying a fastener into the annulus while the first and second magnets are coupled.

31. The method of claim 30, wherein a single catheter device is used to apply the fastener and place the second magnet adjacent the annulus.

32. A system for modifying an annulus of a heart valve to reduce regurgitation of blood through the valve, comprising:

a first catheter,

a first magnet coupled with said first catheter in such a manner that said first catheter is operative to deliver said first magnet adjacent to the annulus,

a second catheter,

a second magnet coupled with said second catheter in such a manner that said second catheter is operative to deliver said second magnet adjacent to the annulus, and

a fastener delivery device coupled to at least one of said first and second catheters and configured to secure a first fastener to the annulus.

33. The system of claim 32, wherein said fastener delivery device comprises a steerable catheter portion so as to enable delivery of a fastener to a desired position.

34. The system of claim 33, wherein said fastener delivery device is coupled at predetermined angle relative to an axis of magnetic attraction between said first and second magnets.

35. The system of claim 32, further comprising a plurality of fastener delivery devices coupled to at least one of said first and second catheters and configured to deliver respective fasteners at spaced apart locations along the annulus.

36. The system of claim 35, further comprising the plurality of fasteners coupled together with at least one flexible tensile member such that said flexible tensile member is capable of drawing the fasteners together and thereby reducing the circumferential length of the annulus.

37. The system of claim 32, wherein said fastener delivery device further comprises a catheter portion, and further comprising:

an RF powered element extendable from within said catheter portion and operable to form an aperture in the annulus for insertion of the fastener.

38. The system of claim 32, wherein at least one of said first and second catheters is coupled with an inflatable member configured to stabilize said fastener delivery device adjacent the annulus.

39. The system of claim 32, wherein said fastener delivery device is a catheter portion, and further comprising:

said first fastener coupled with a flexible tensile member and received within said catheter portion, said first fastener and flexible tensile member deployable through said catheter portion.

40. The system of claim 39, wherein said first fastener further comprises a torsion spring member configured to expand after deployment from said catheter portion.

41. The system of claim 40, wherein said torsion spring member locks against said flexible tensile member upon deployment from said catheter portion.

42. The system of claim 39, further comprising:

a second fastener coupled with said flexible tensile member, at least one of said first and second fasteners movable along and then lockable to said flexible tensile member thereby allowing a distance between said first and second fasteners to be shortened and locked resulting in a shortening of the circumferential length of the annulus.

43. A catheter adapted to be a guide element placed within a vessel, comprising:

a distal support portion, and

first and second magnets carried on said distal support portion, said first and second magnets positioned in spaced apart relation such that a gap is formed between said first and second magnets and repelling poles face each other, whereby a circumferential virtual magnetic pole emanates around the gap between said first and second magnets.

44. A catheter system for modifying an annulus of a heart valve to reduce regurgitation of blood flow through the valve, comprising:

a catheter having at least one lumen,

first and second fasteners coupled together by a flexible tensile member and adapted to be secured to heart tissue proximate the annulus, and

a rod movable between a compact state within said lumen and an expanded state outside of said lumen, said first and second fasteners further coupled to said rod such that said first fastener is movable along the rod relative to said second fastener by applying tension to said flexible tensile member.

45. The system of claim 44, wherein said rod is generally C-shaped in said expanded state so as to follow the annulus.

46. The system of claim 44, further comprising a third fastener coupled for movement along said rod and adapted to be secured to heart tissue proximate the annulus.

47. The system of claim 46, further comprising a second flexible tensile member secured to said third fastener, said third fastener being movable along the rod relative to said second fastener by applying tension to said second flexible tensile member.

48. The system of claim 44, further comprising:

a magnet connected to said rod and adapted to magnetically couple with a magnet in the coronary sinus for stabilizing the position of the rod as said fasteners are secured to the heart tissue.

49. A catheter system for modifying an annulus of a heart valve to reduce regurgitation of blood flow through the valve, comprising:

first, second and third fasteners adapted to be secured to the annulus,

first, second and third flexible tensile members respectively connectable to said first, second and third fasteners, and

a generally V-shaped valve support member having a pair of legs movable between a compact state suitable for carrying said valve support member within a catheter and an expanded state in which said legs are more separated, a

free end of each leg including respective first and second eyelets receiving said first and second flexible tensile members and an apex between said pair of legs including a third eyelet receiving said third flexible tensile member.

50. The system of claim 49, further comprising first, second and third crimp members for respectively securing said first, second and third flexible tensile members with respect to said first, second and third eyelets after at least one of said flexible tensile members is pulled tight to modify the shape of the annulus.

51. A catheter system for modifying an annulus of a heart valve to reduce regurgitation of blood flow through the valve, comprising:

first, second and third fasteners adapted to be secured to the annulus,

first, second and third flexible tensile members respectively connectable to said first, second and third fasteners, and

a generally V-shaped valve support member having a pair of legs movable between a compact state suitable for carrying said valve support member within a catheter and an expanded state in which said legs are more separated, a free end of each leg including respective first and second eyelets receiving said first and second flexible tensile members and an apex between said pair of legs including a third eyelet receiving said third flexible tensile member.

52. The system of claim 49, further comprising first, second and third crimp members for respectively securing said first, second and third flexible tensile members with respect to said first, second and third eyelets after at least one of said flexible tensile members is pulled tight to modify the shape of the annulus.

53. A catheter system for modifying an annulus of a heart valve to reduce regurgitation of blood flow through the valve, comprising:

a catheter having at least one lumen,

first and second fasteners adapted to be secured to the annulus,

at least one flexible tensile member coupling said first and second fasteners together, and

a crimping device deployable through said catheter and including a crimp and a compression applying mechanism configured to compress said crimp onto said at least one flexible tensile member after said fasteners are pulled

toward one another with said at least one flexible tensile member to reduce the circumferential length of the annulus.

54. The system of claim 53, further comprising a cutting mechanism associated with said crimping device and configured to cut said at least one flexible tensile member after compression of said crimp.

55. The system of claim 53, further comprising a third fastener adapted to be secured to the heart tissue, and wherein separate flexible tensile members are connected with each of said fasteners and threaded through said crimp.

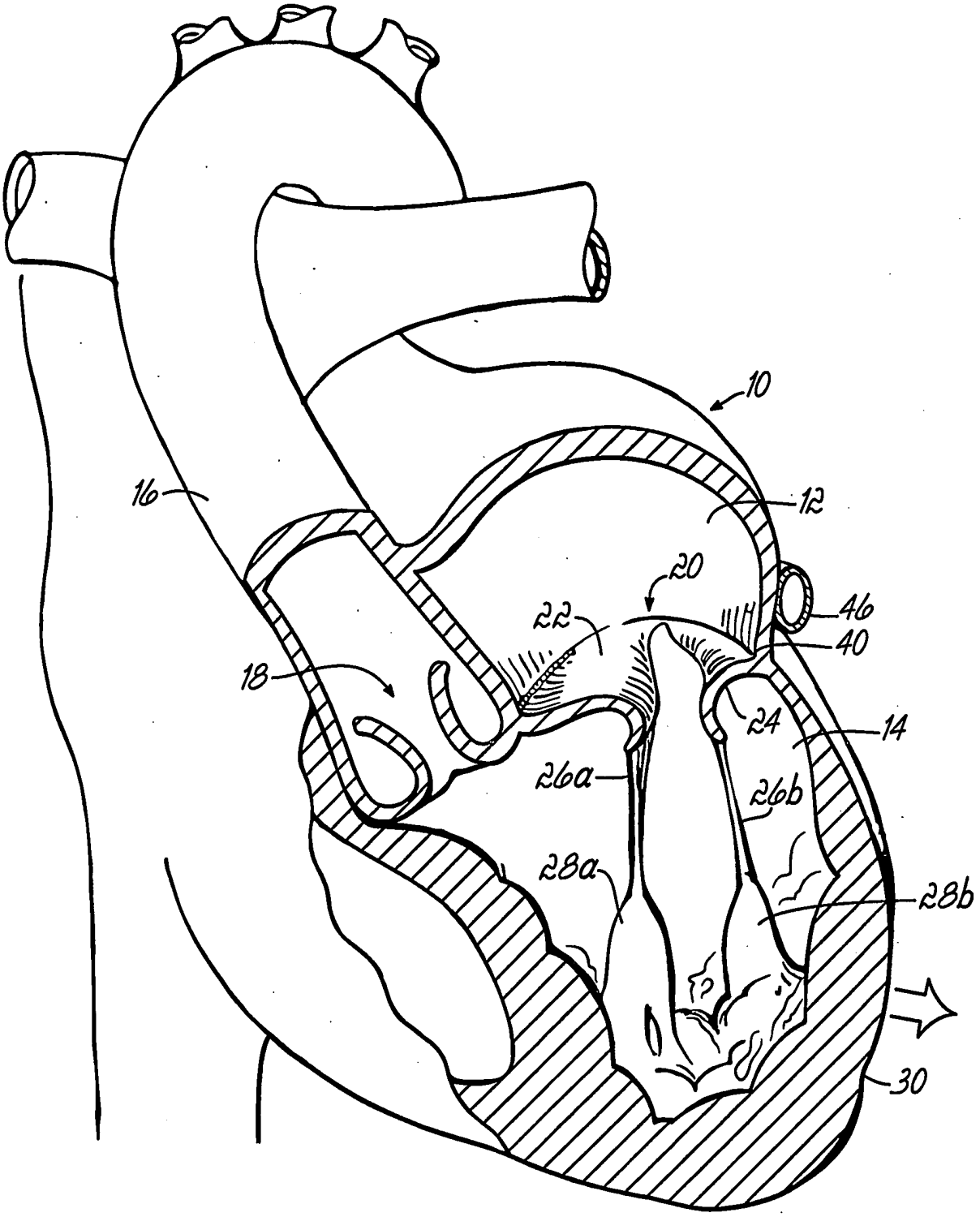
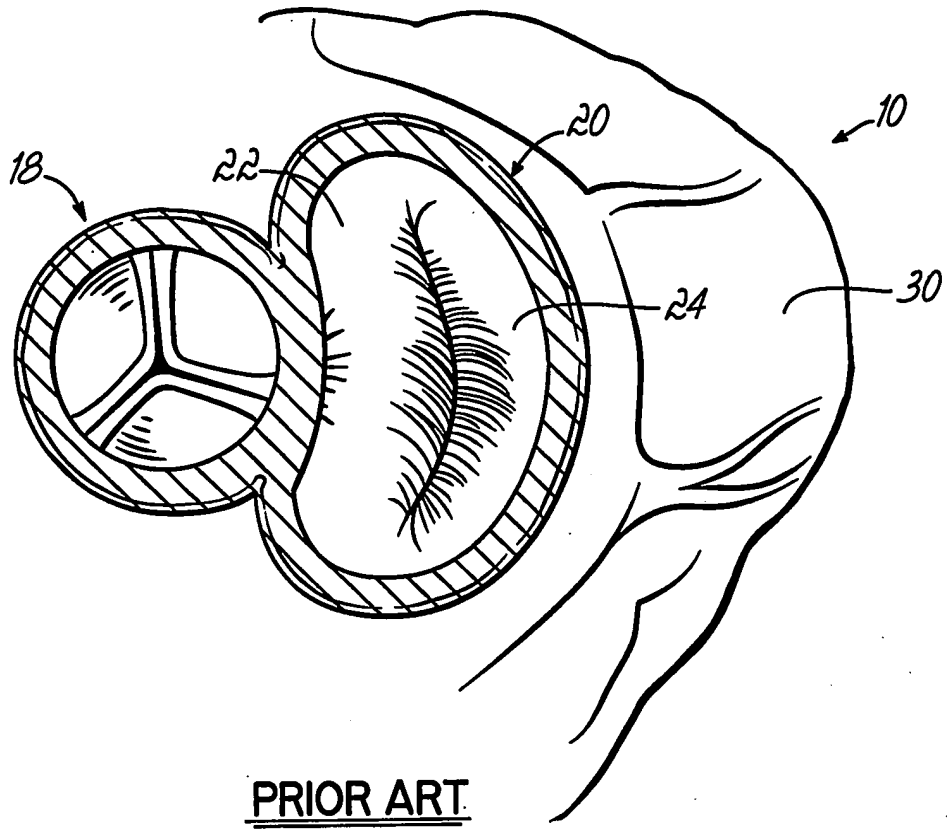
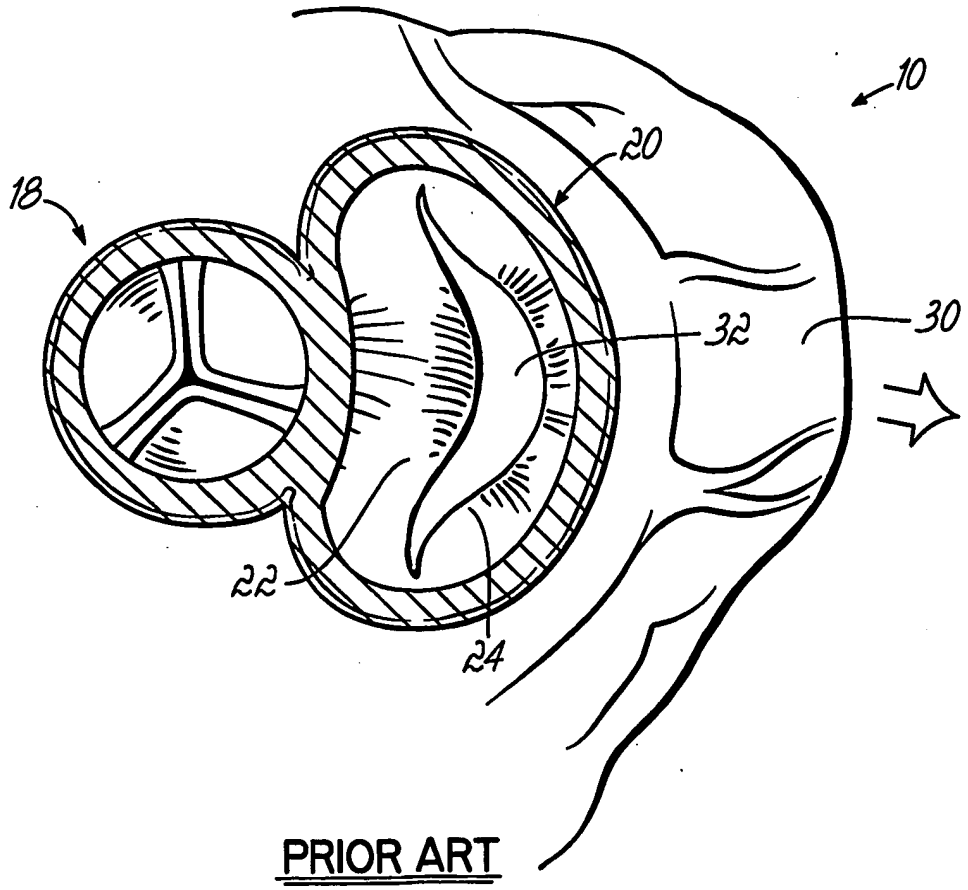


FIG. A



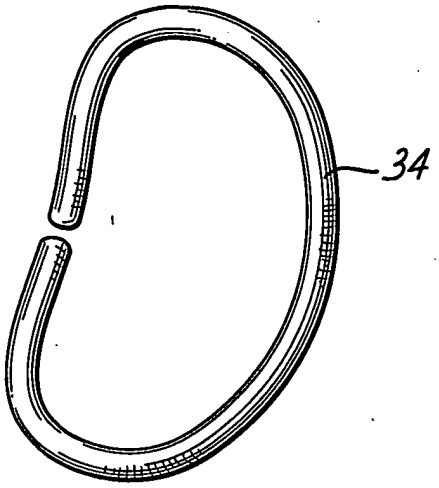
PRIOR ART

FIG. B



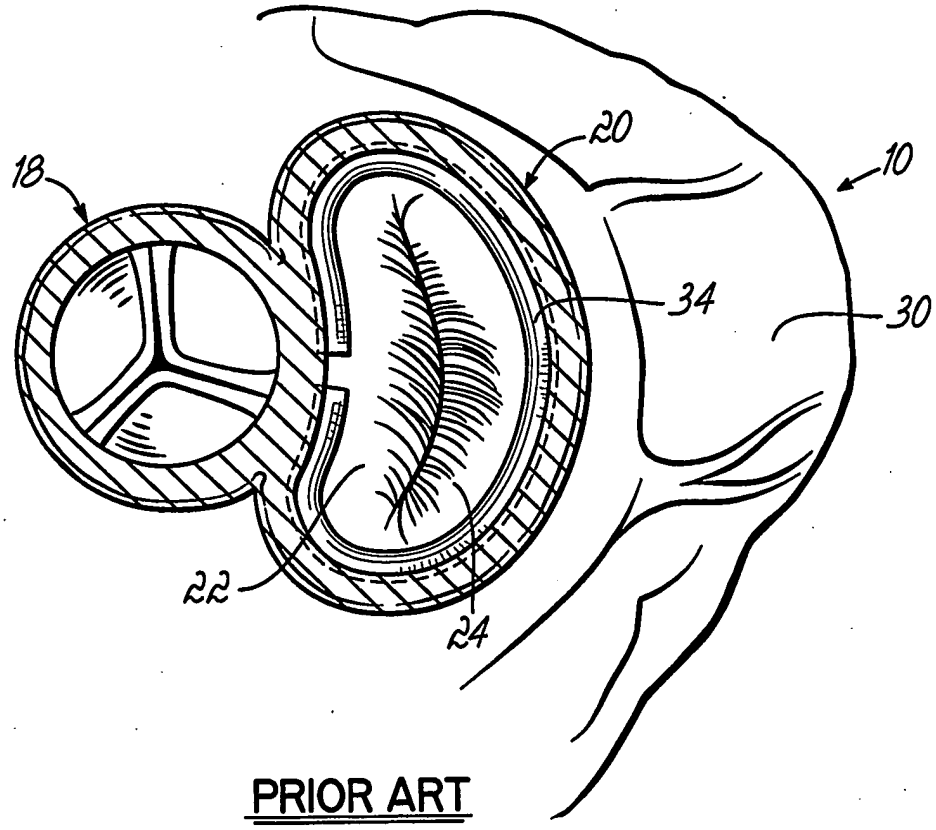
PRIOR ART

FIG. C



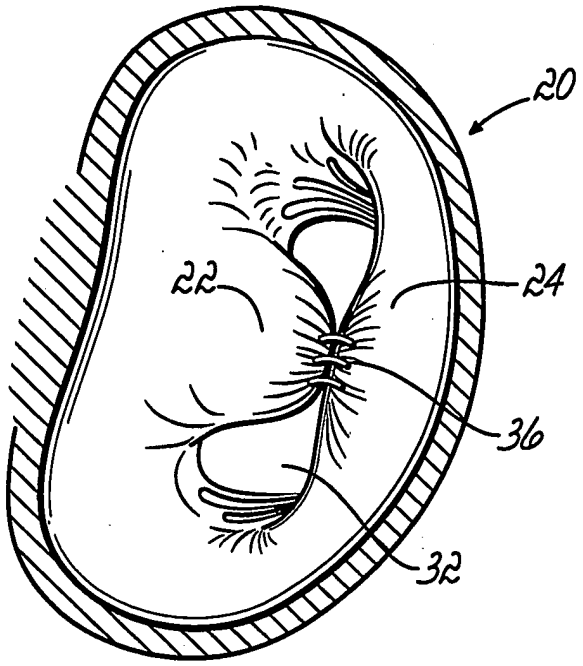
PRIOR ART

FIG. D



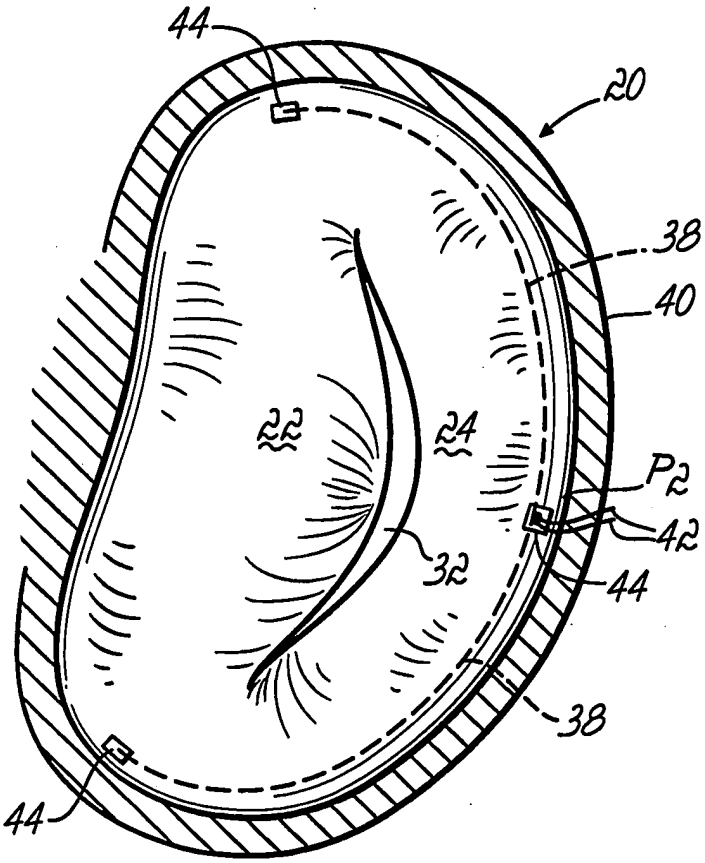
PRIOR ART

FIG. E



PRIOR ART

FIG. F



PRIOR ART

FIG. G

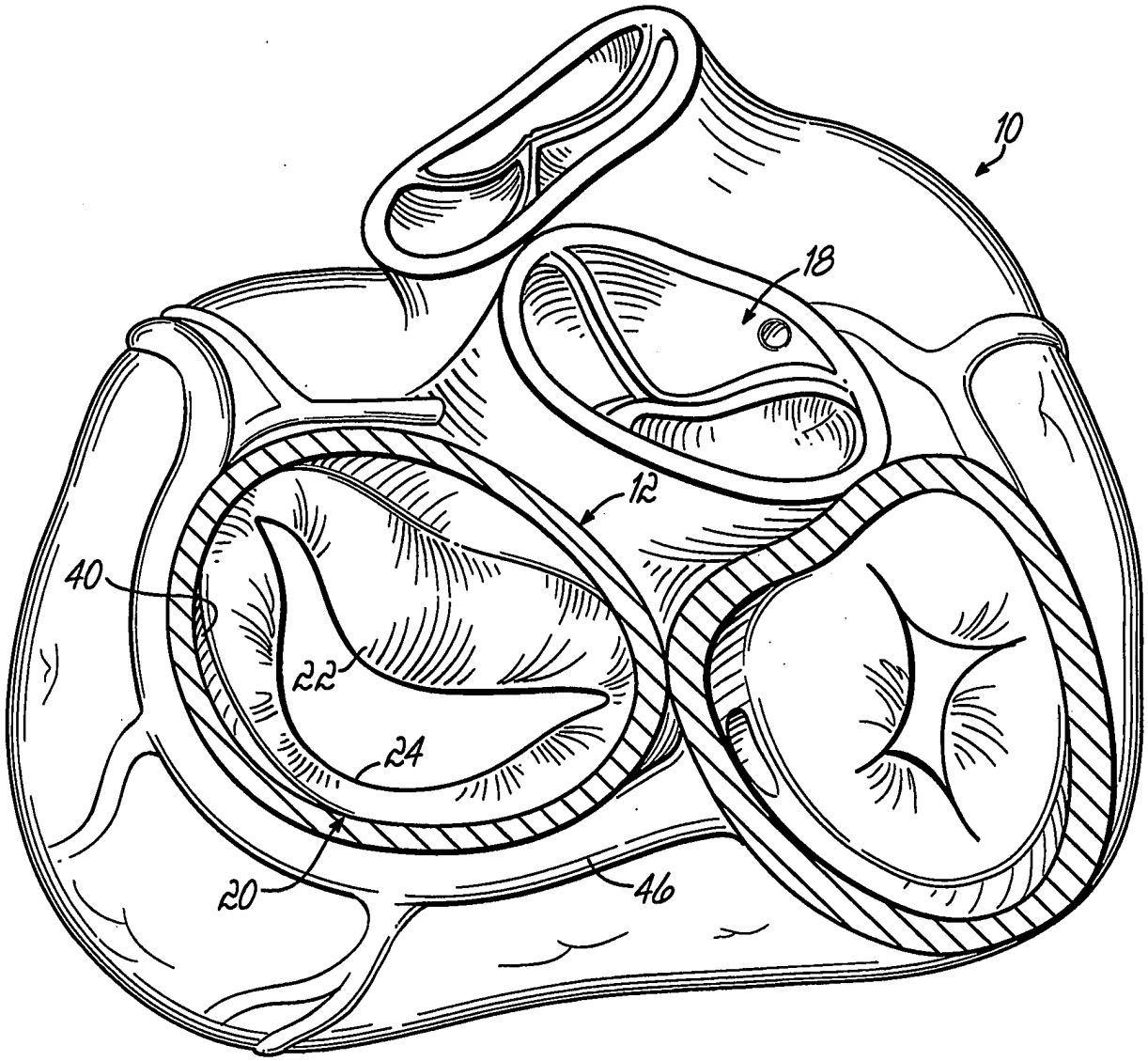
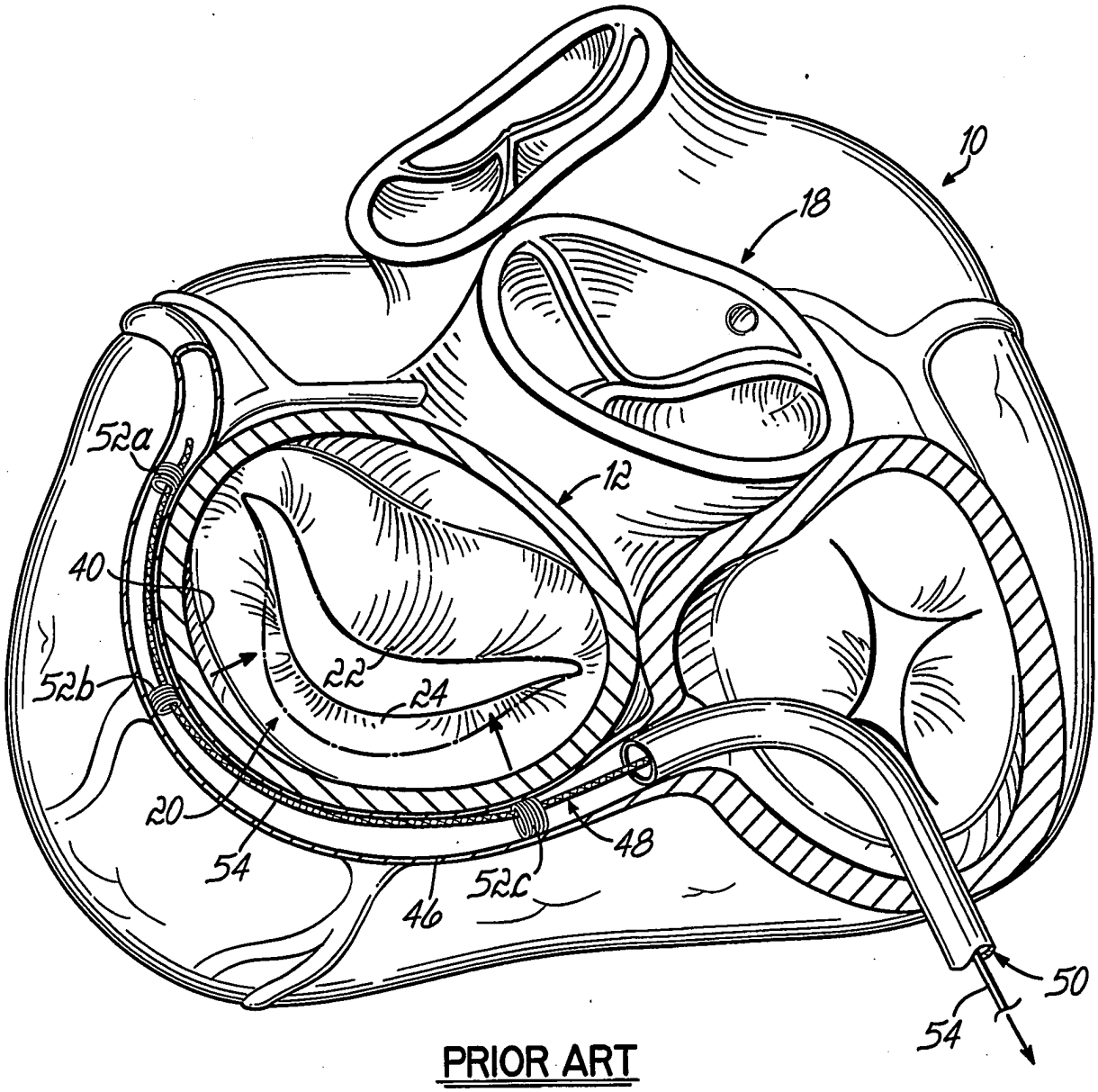


FIG. H



PRIOR ART

FIG. I

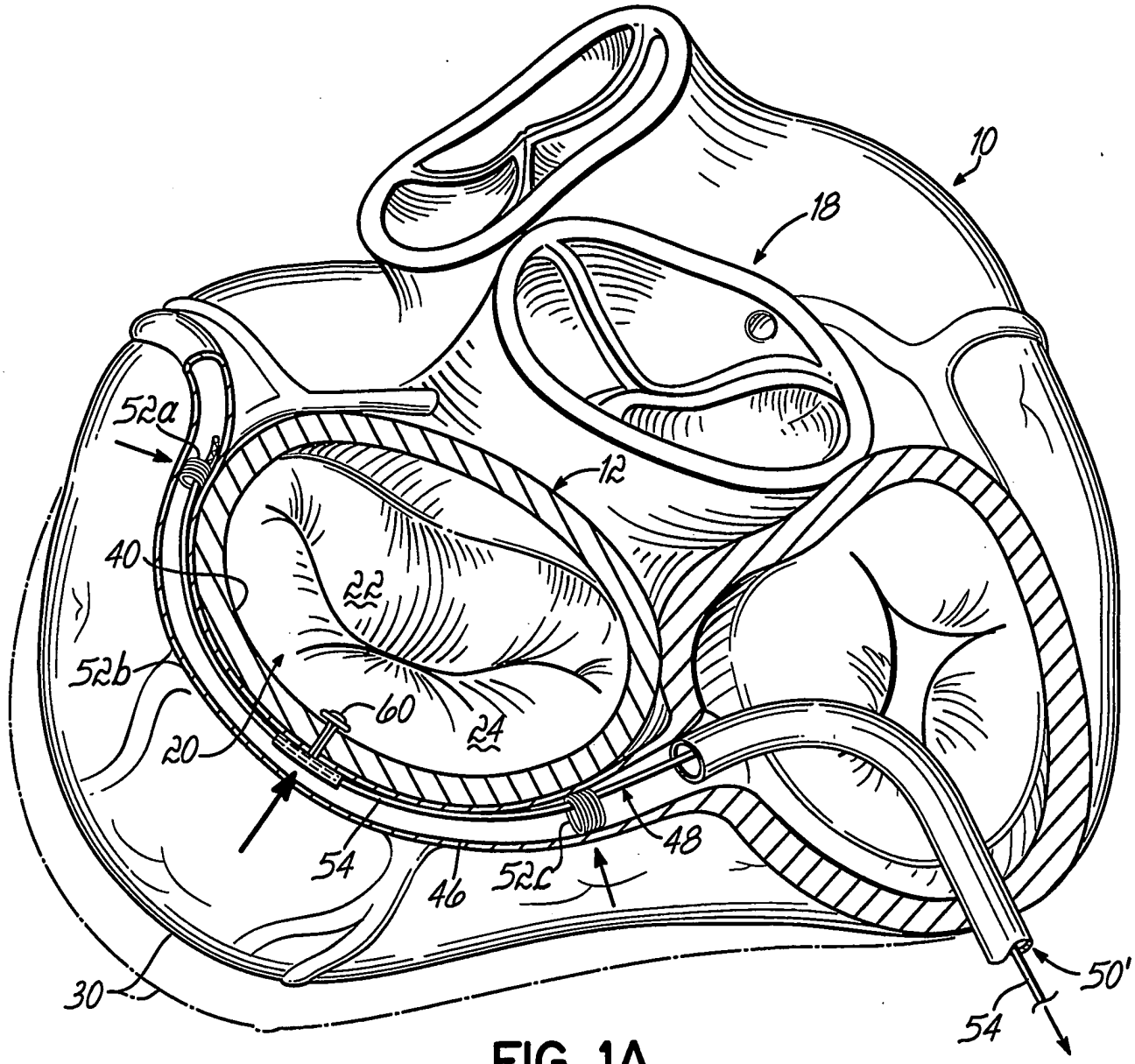


FIG. 1A

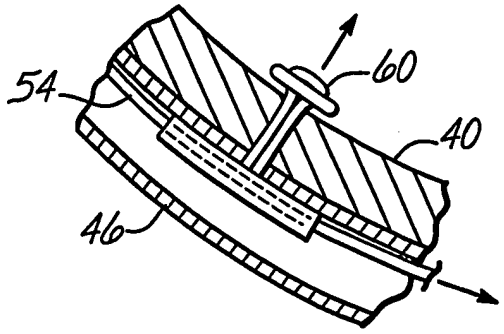


FIG. 1B

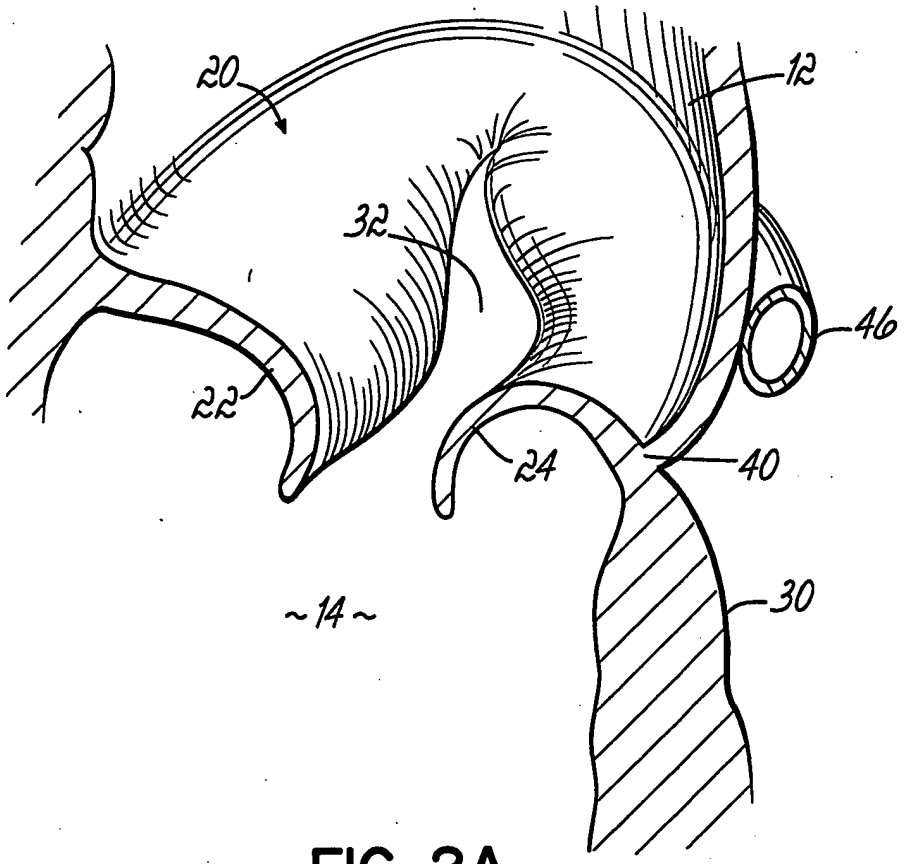


FIG. 2A

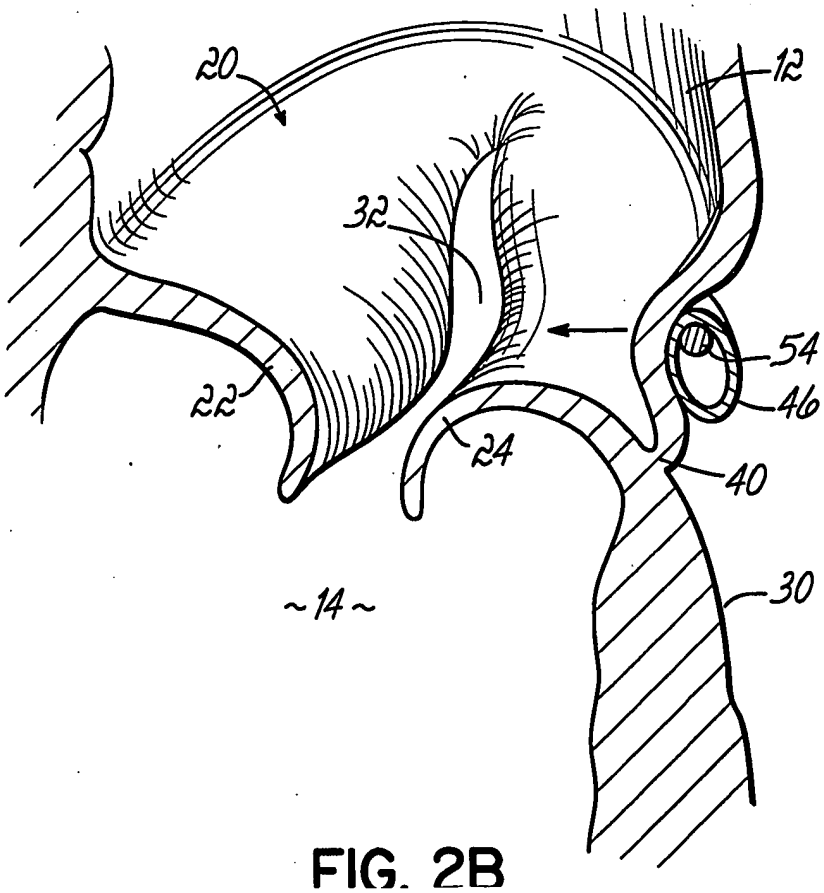


FIG. 2B

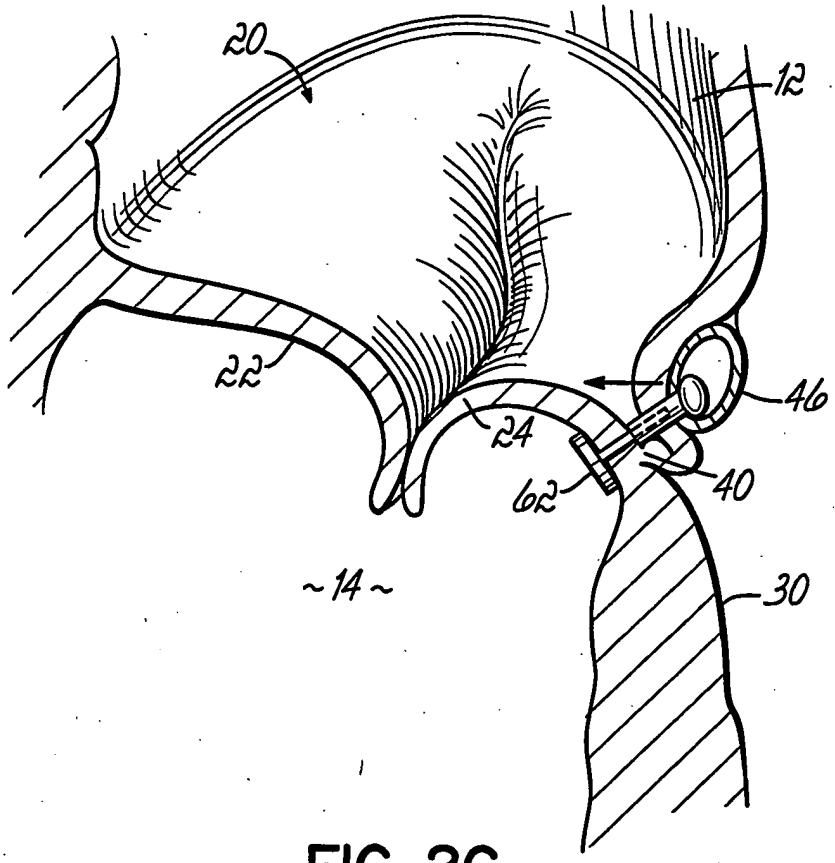


FIG. 2C

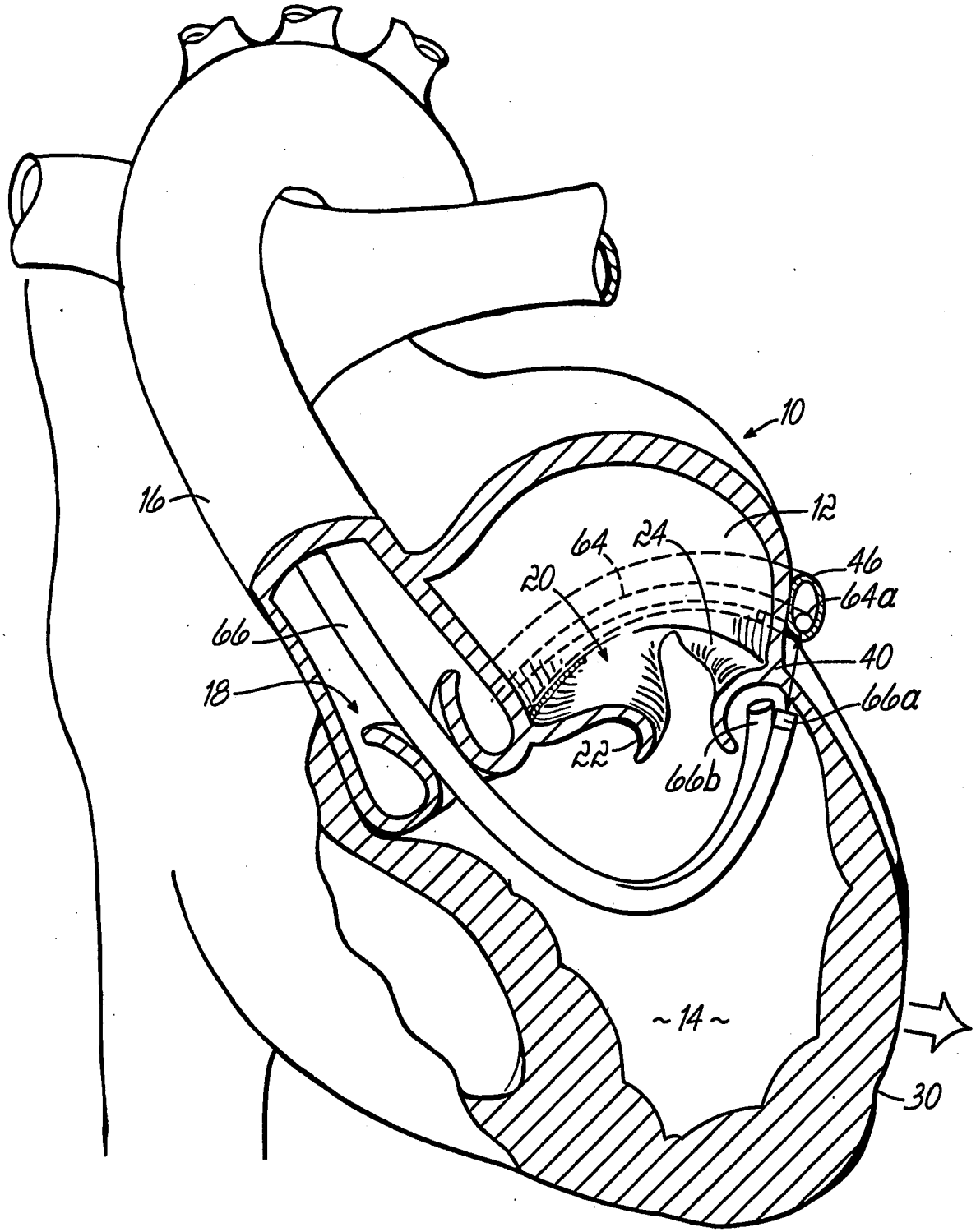


FIG. 3

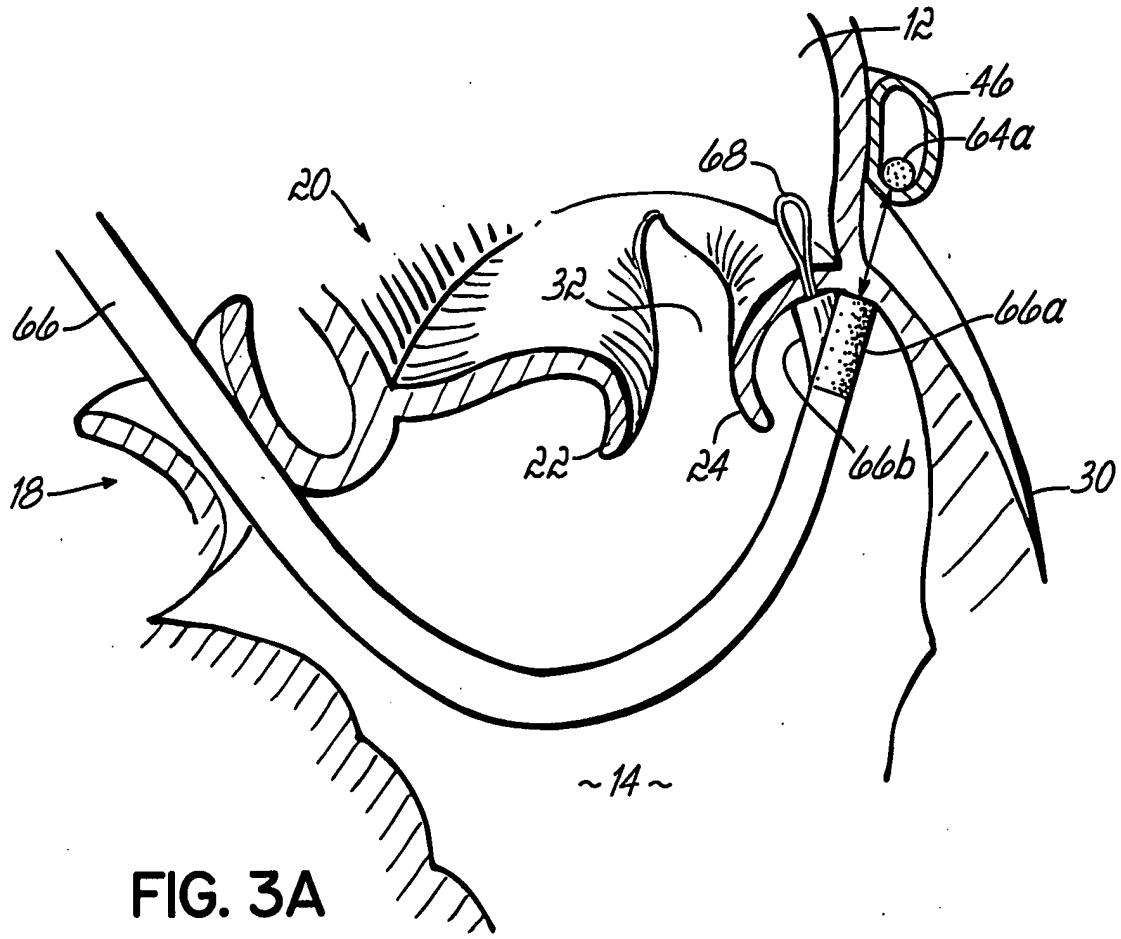

12
46
64a
68
20
32
66a
66
18
22
24
66b
30
~14~

FIG. 3A

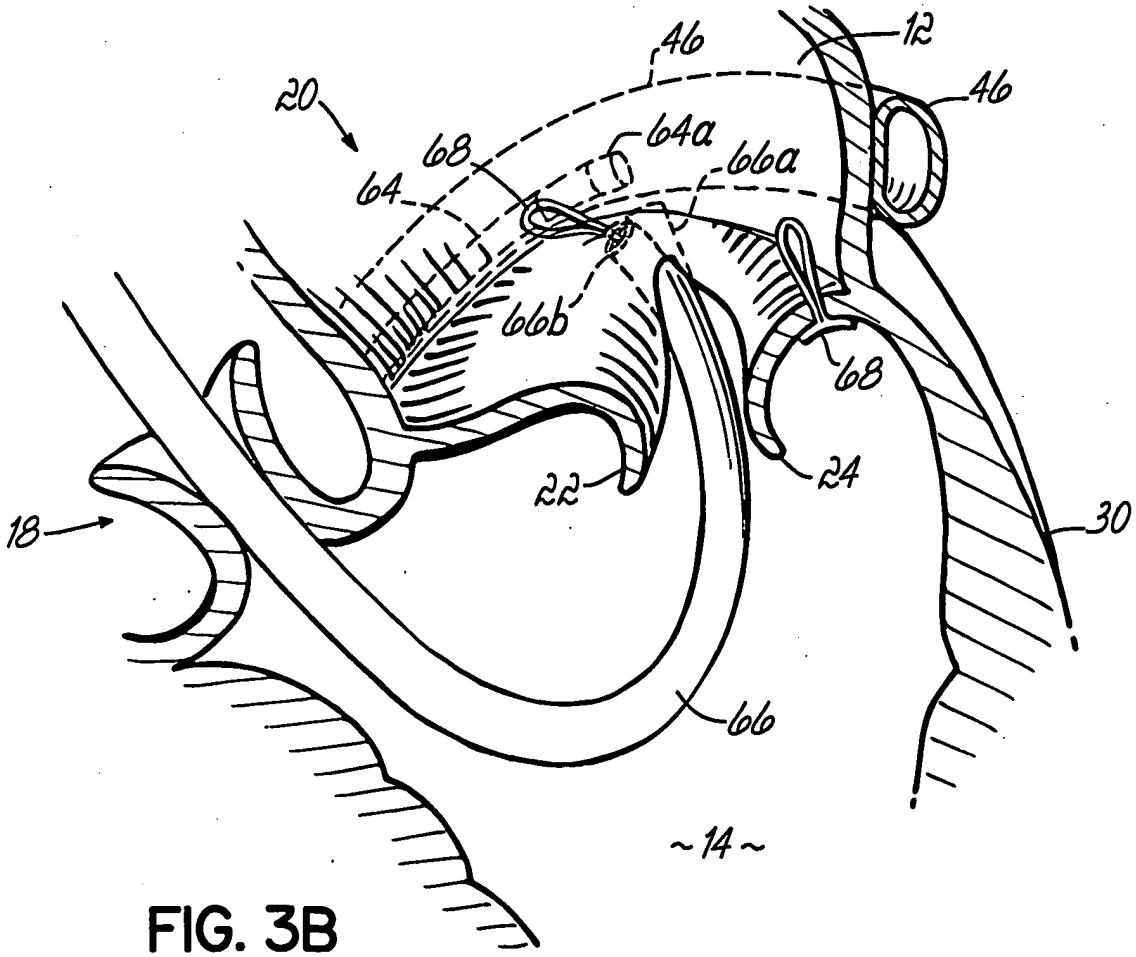

46
12
20
46
68
64a
66a
64
66b
68
24
22
30
18
66
~14~

FIG. 3B

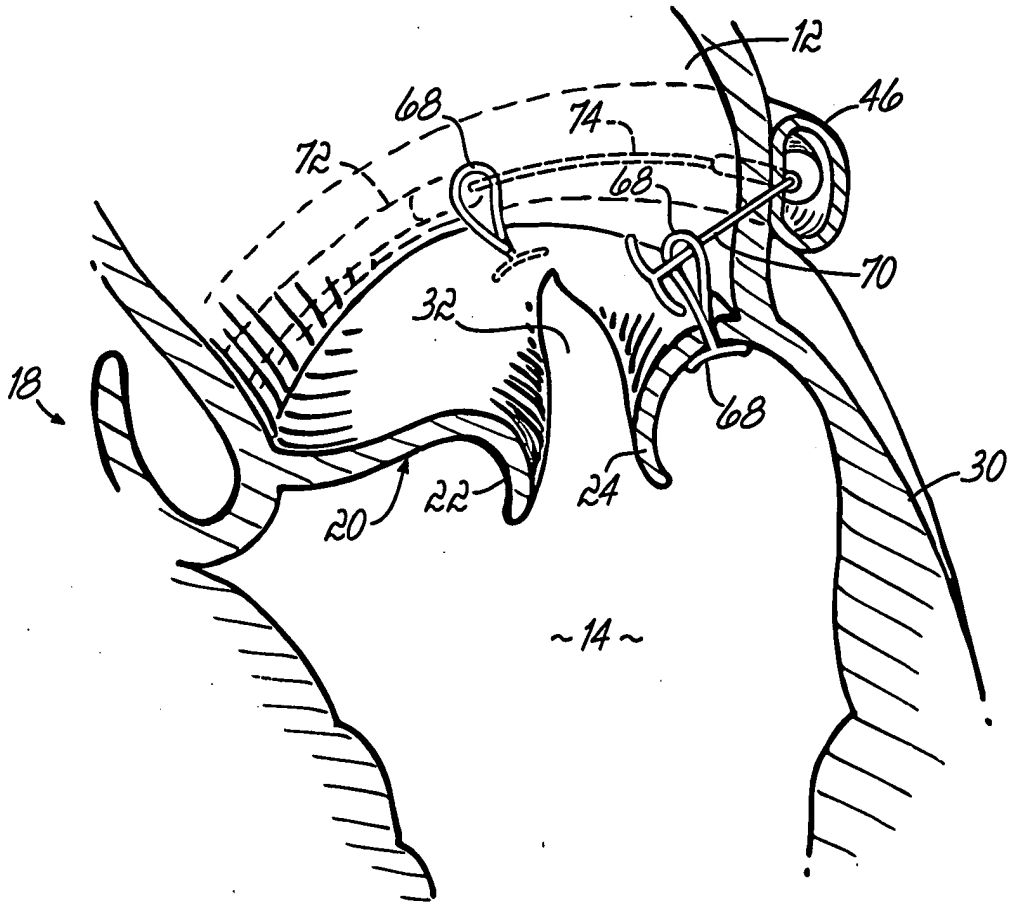

12
46
68
74
72
68
70
32
18
68
30
20
22
24
~14~

FIG. 3C

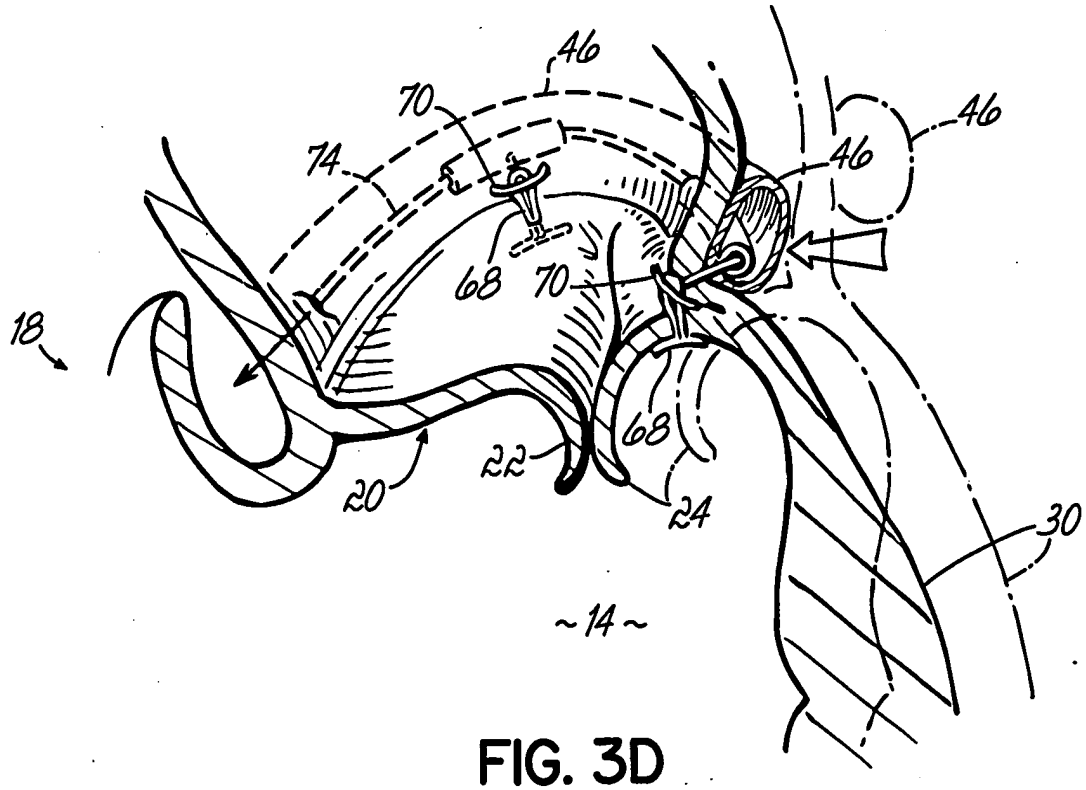

46
70
46
46
74
68
70
18
68
22
20
24
30
~14~

FIG. 3D

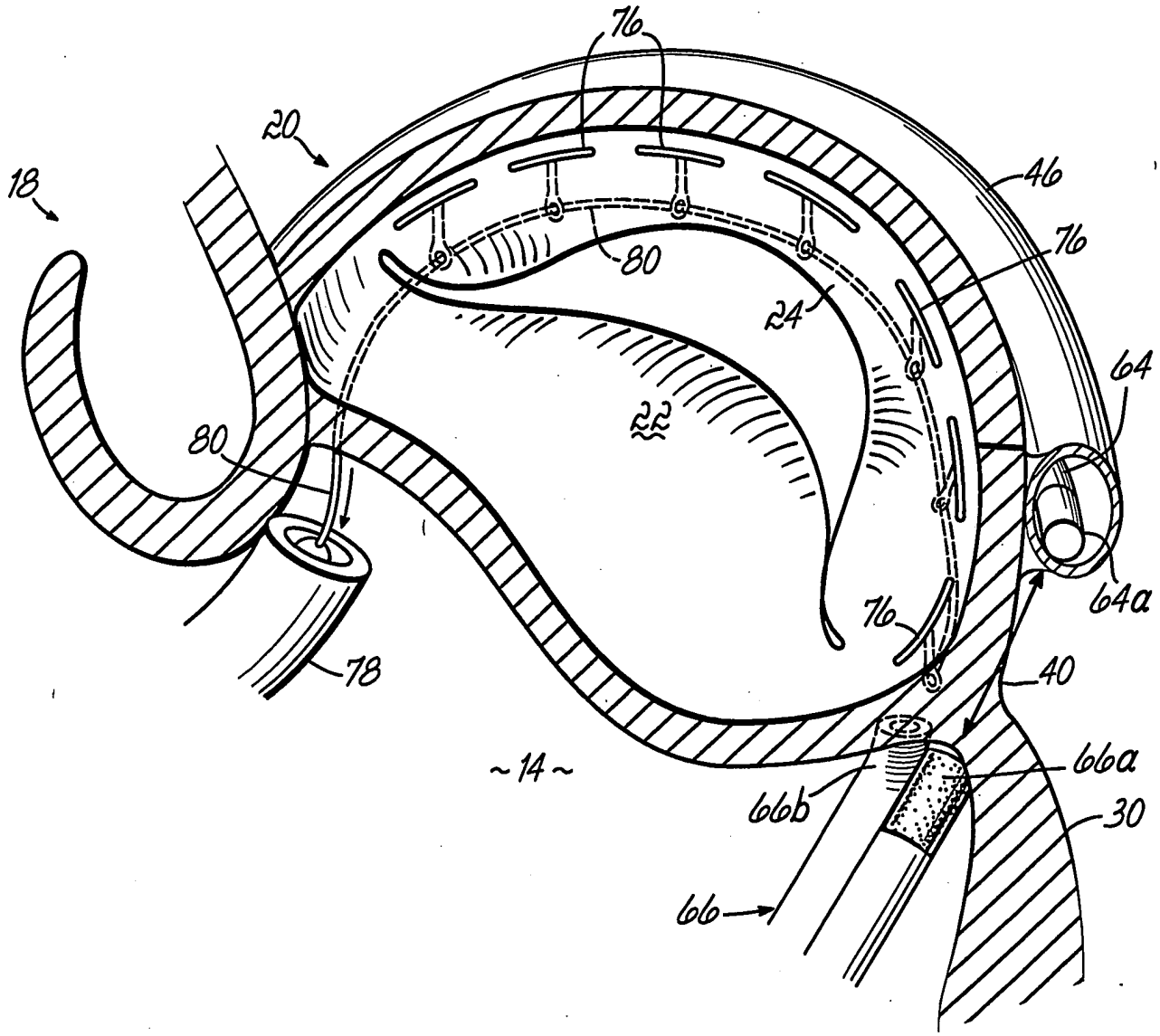


FIG. 4

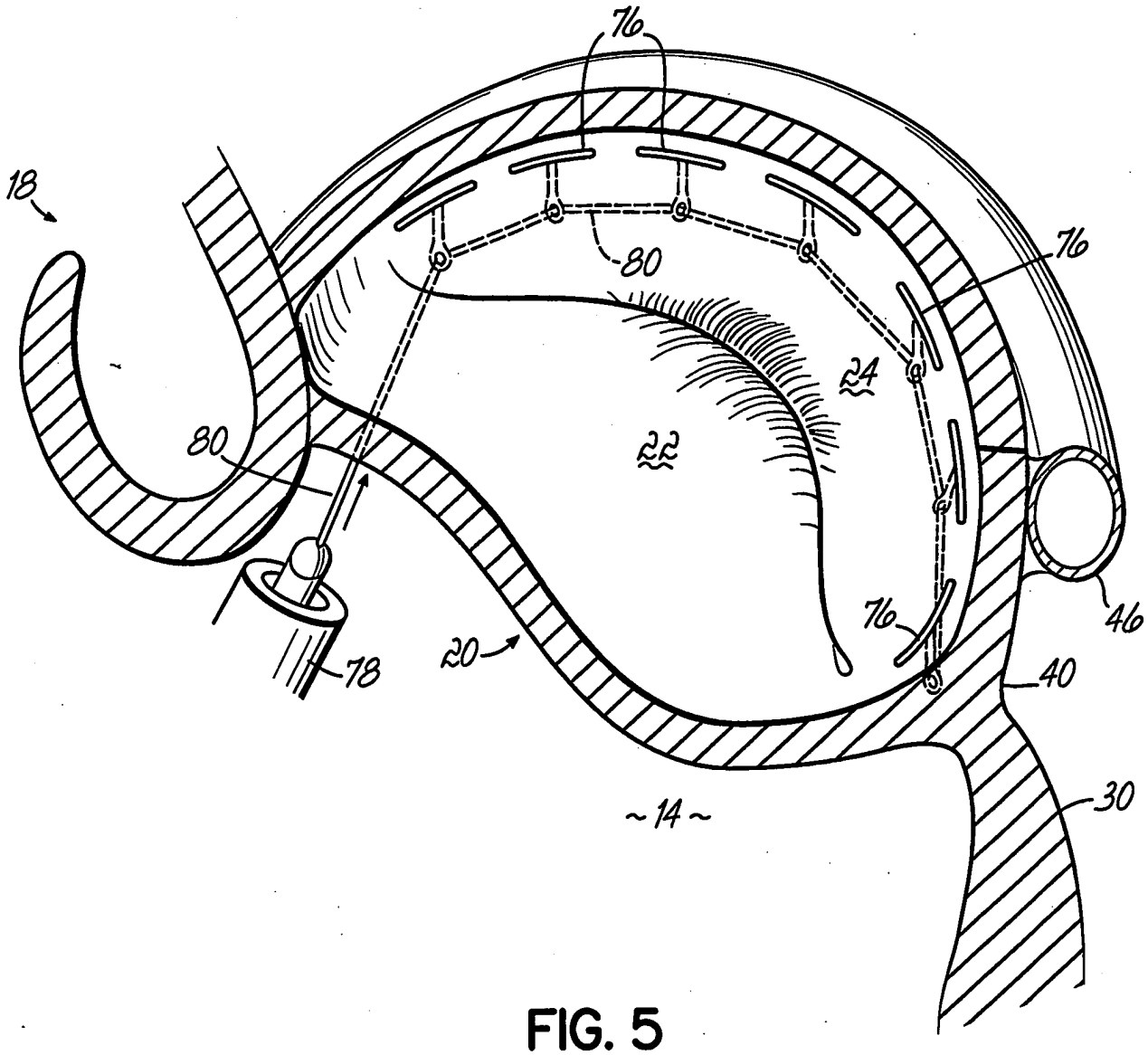


FIG. 5

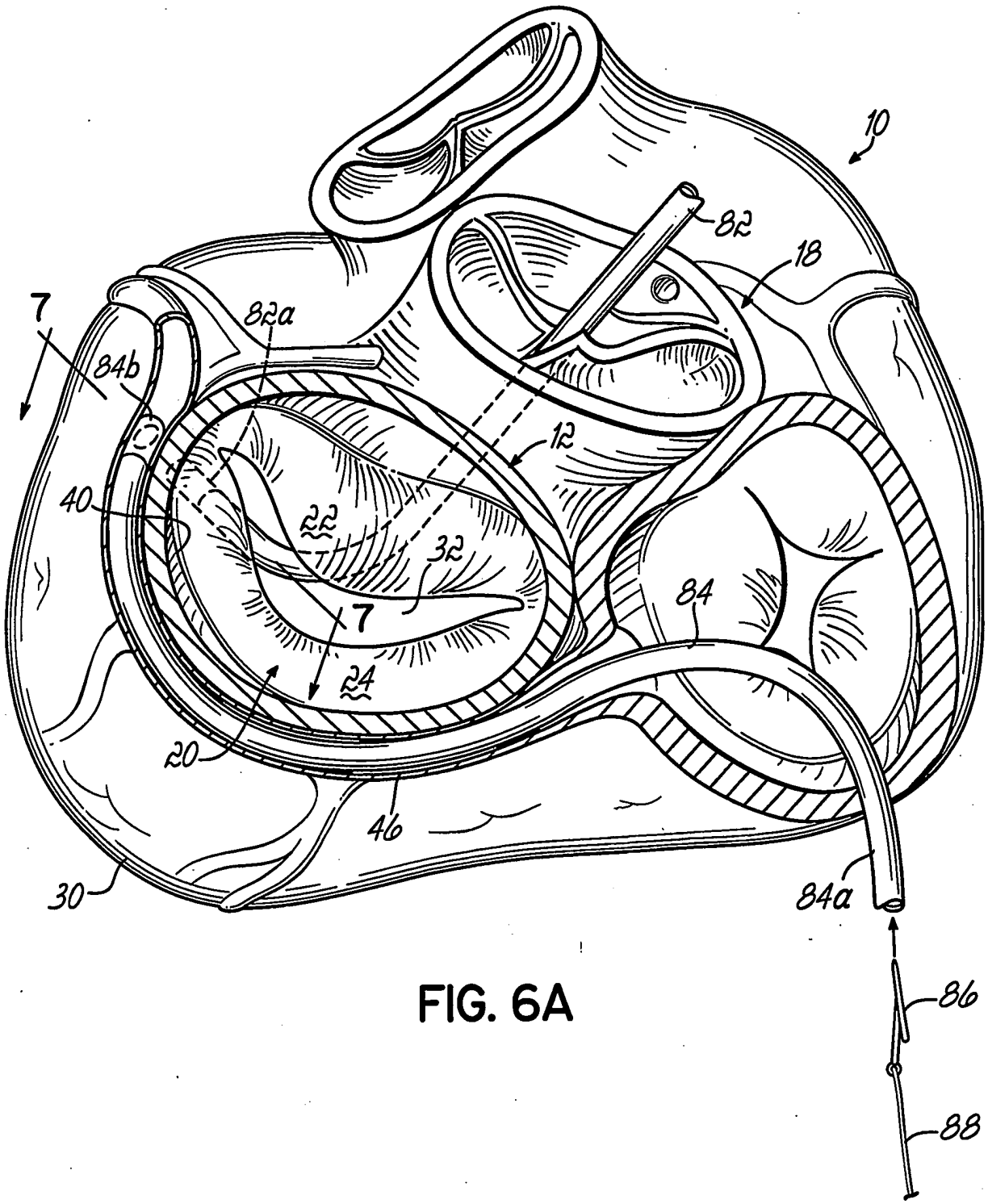


FIG. 6A

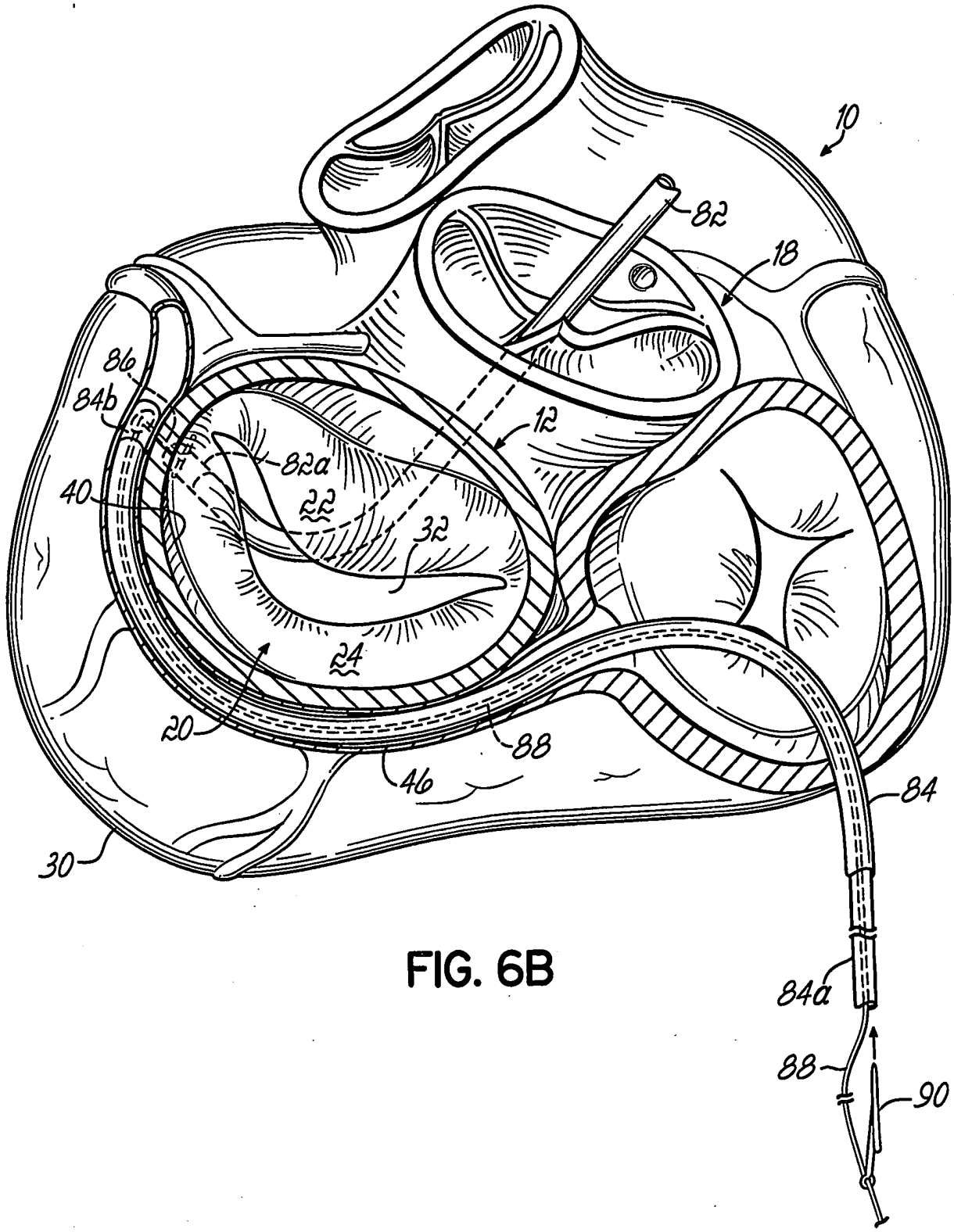


FIG. 6B

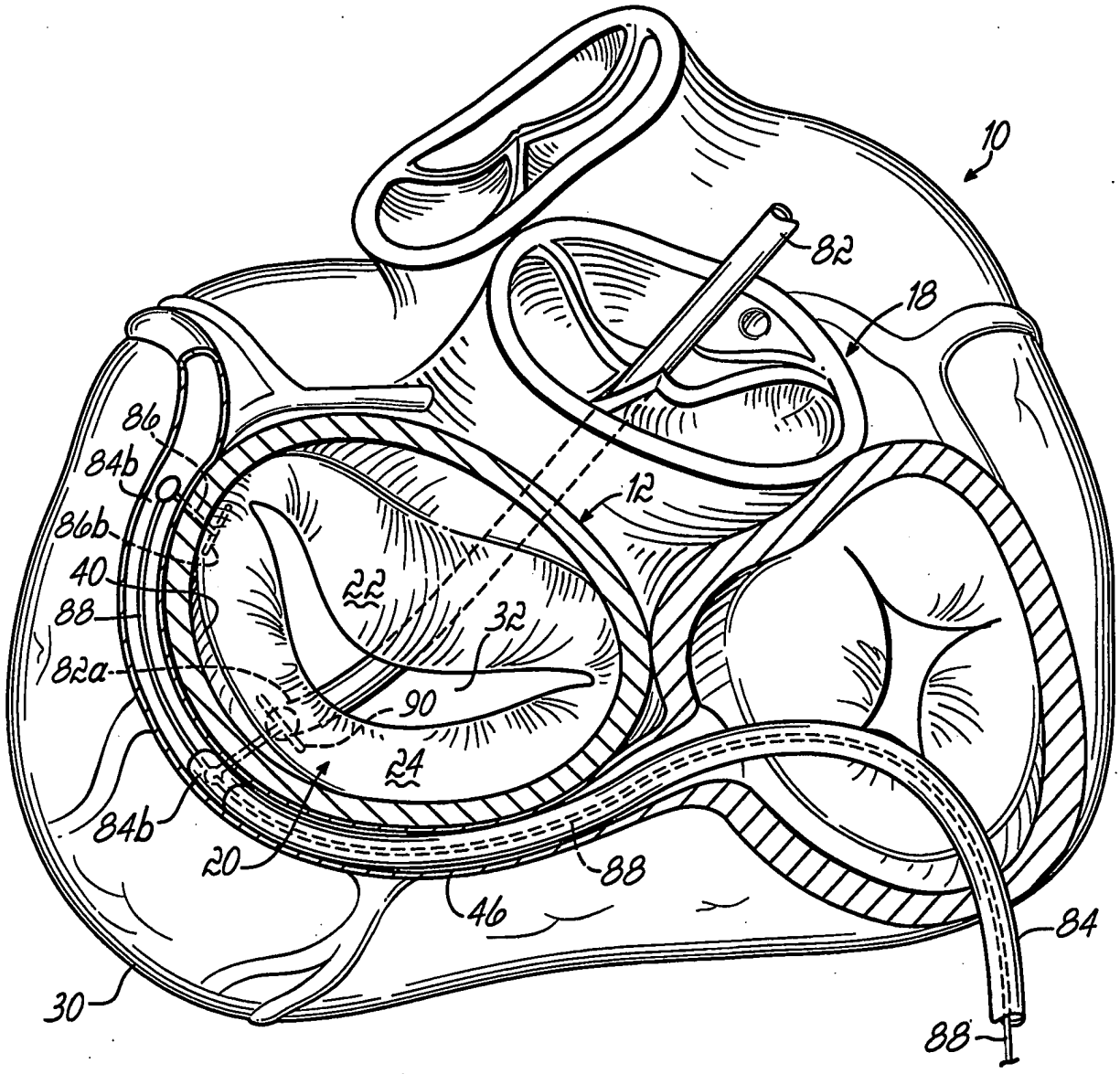


FIG. 6C

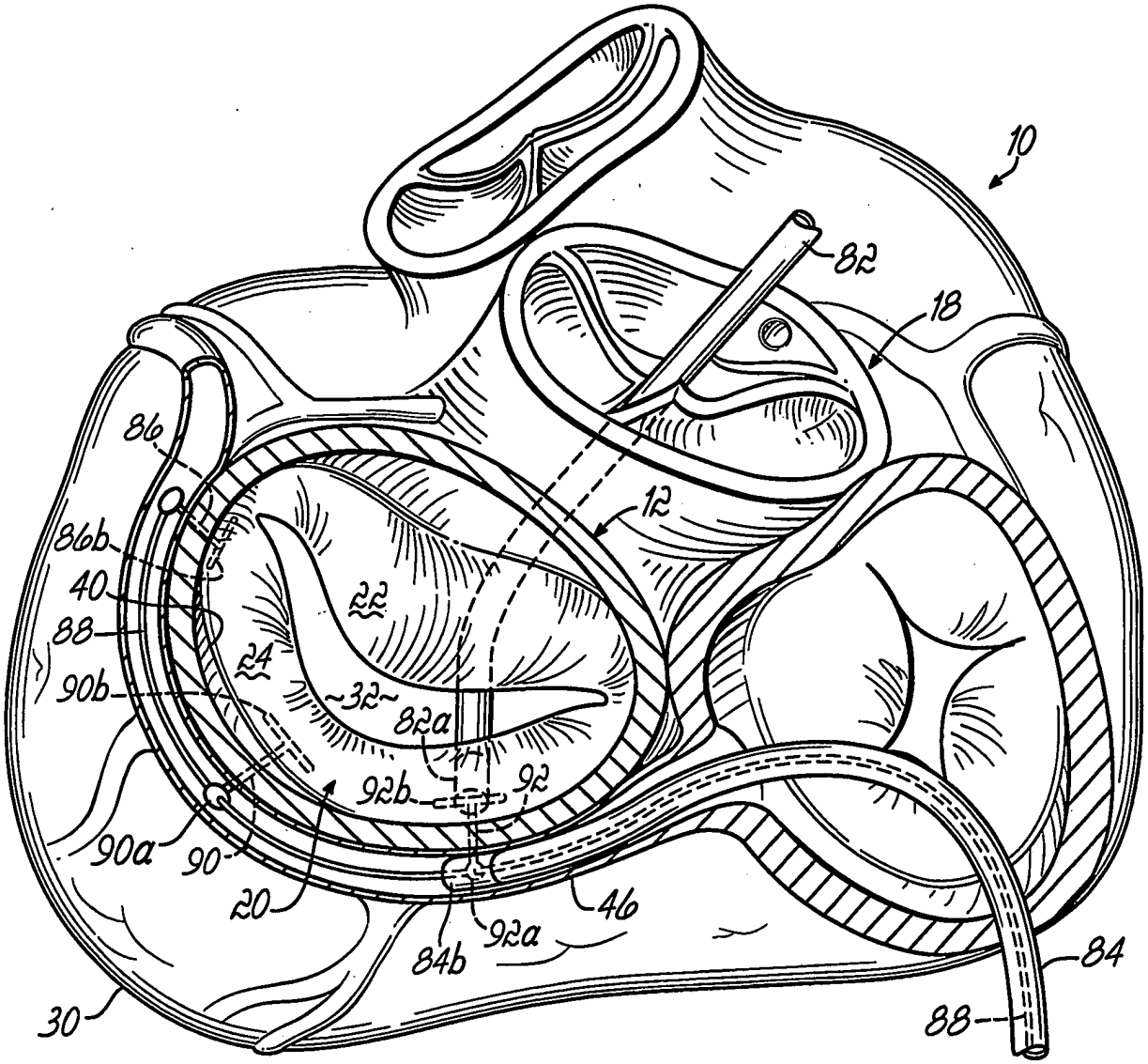

10
82
18
86
12
86b
40
22
88
24
90b
32
82a
92b
92
90a
90
20
46
92a
84b
84
30
88

FIG. 6D

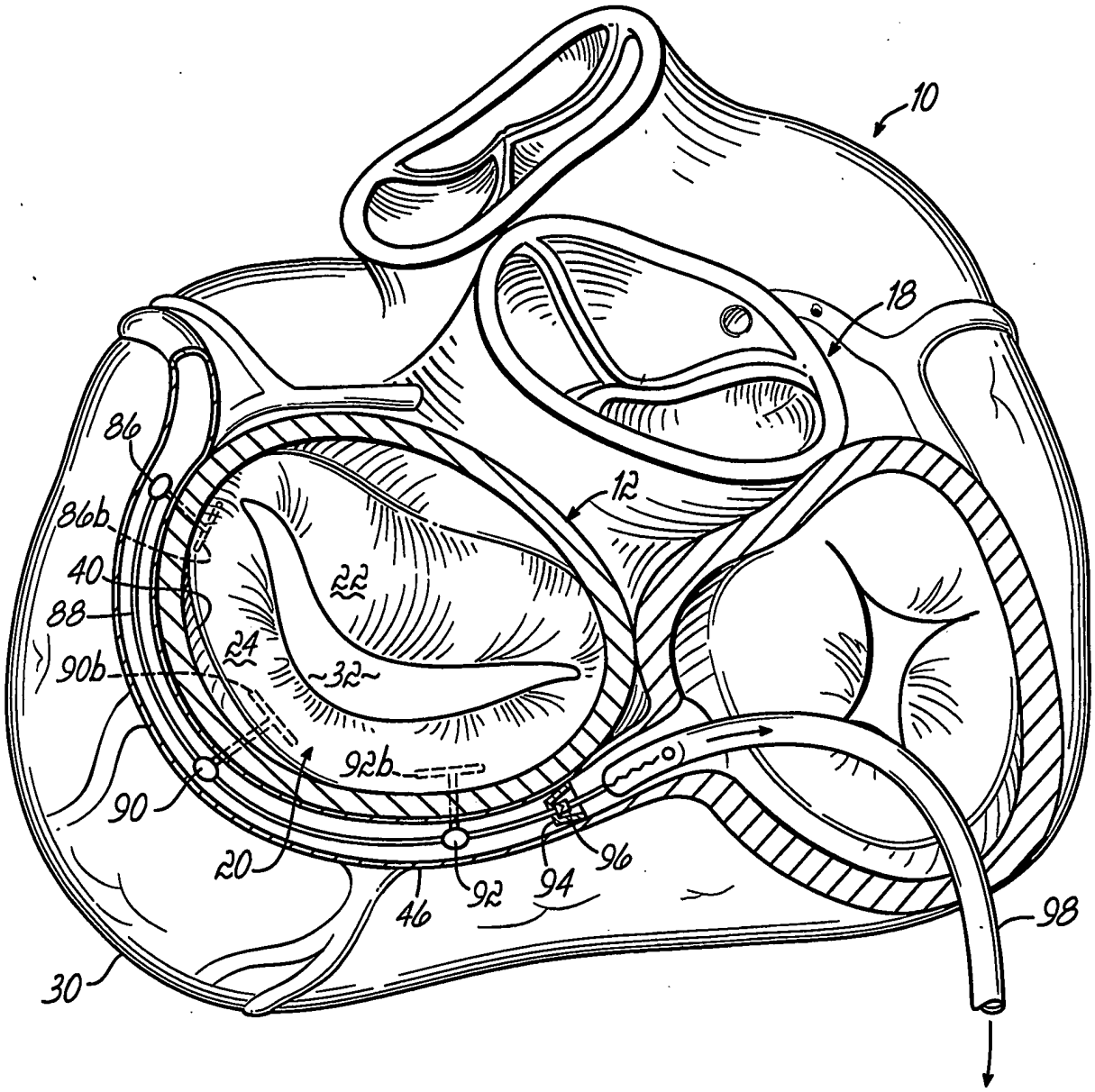


FIG. 6E

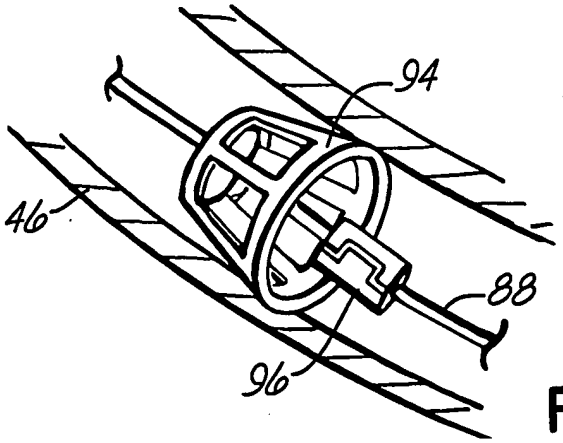


FIG. 6E-1

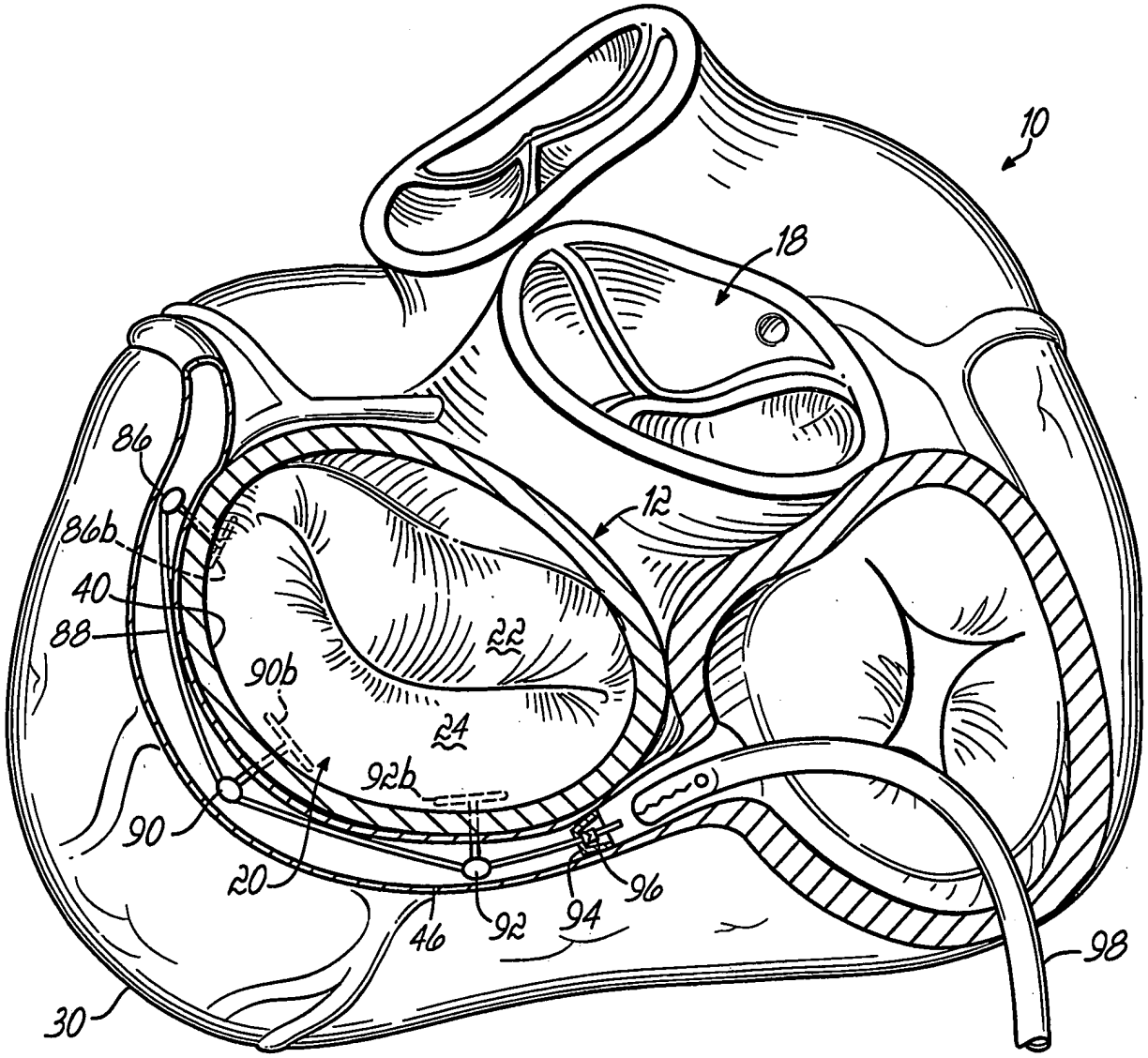


FIG. 6F

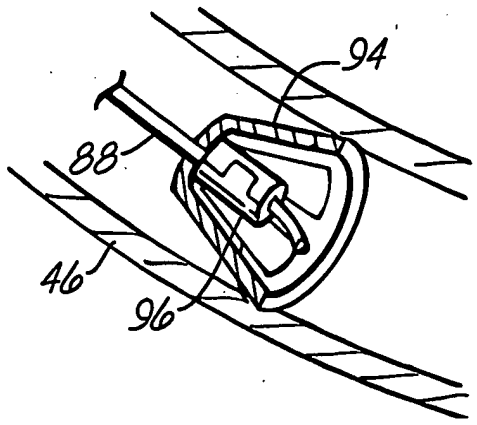


FIG. 6F-1

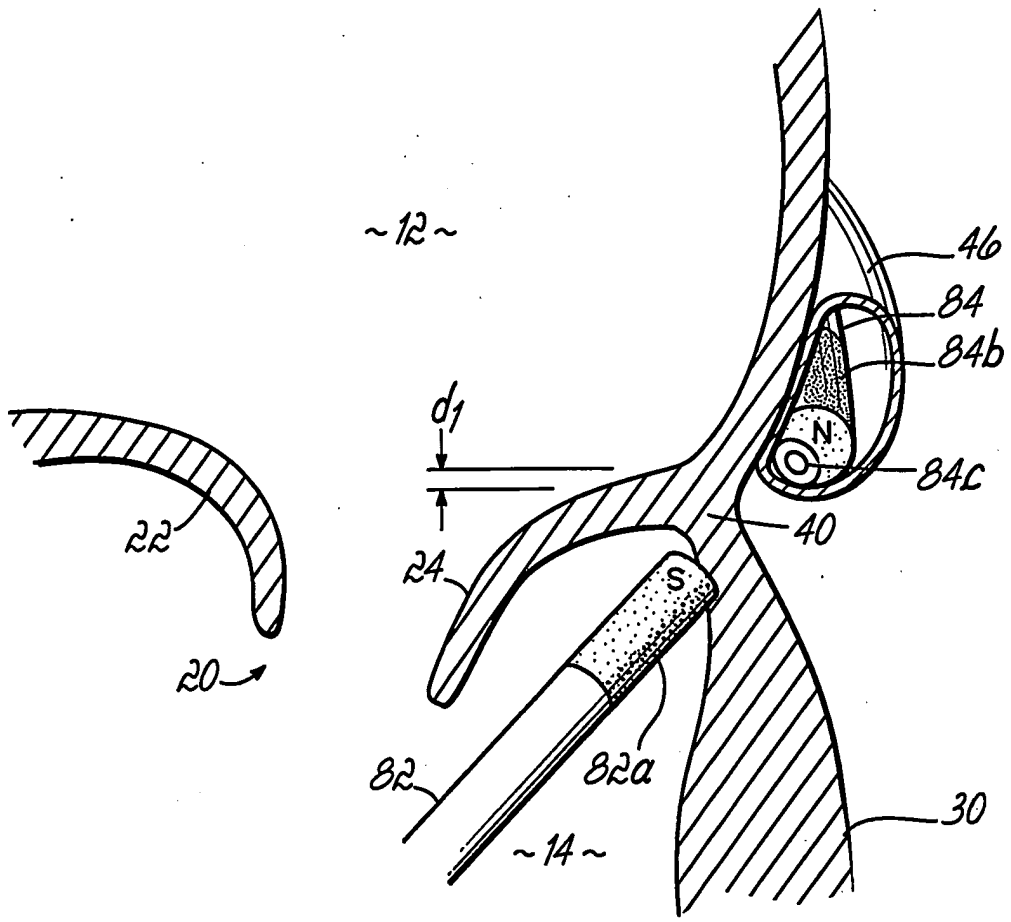


FIG. 7A

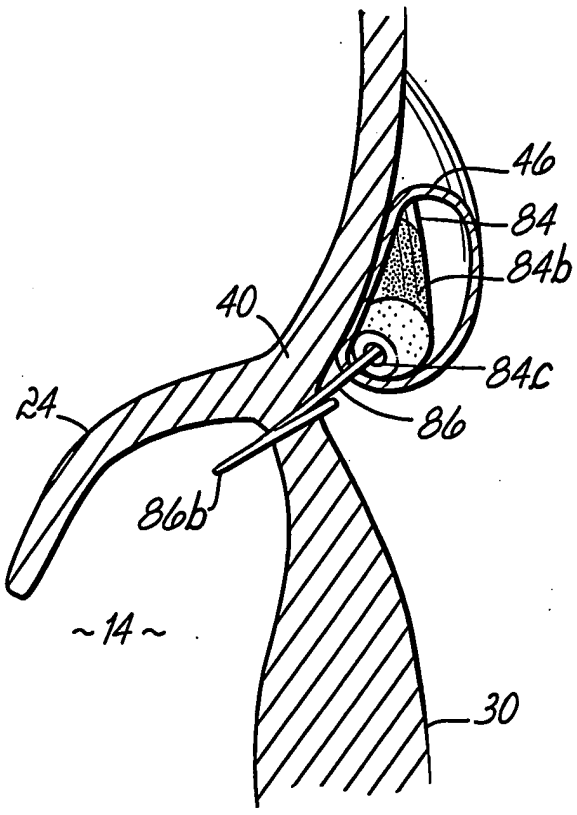


FIG. 7B

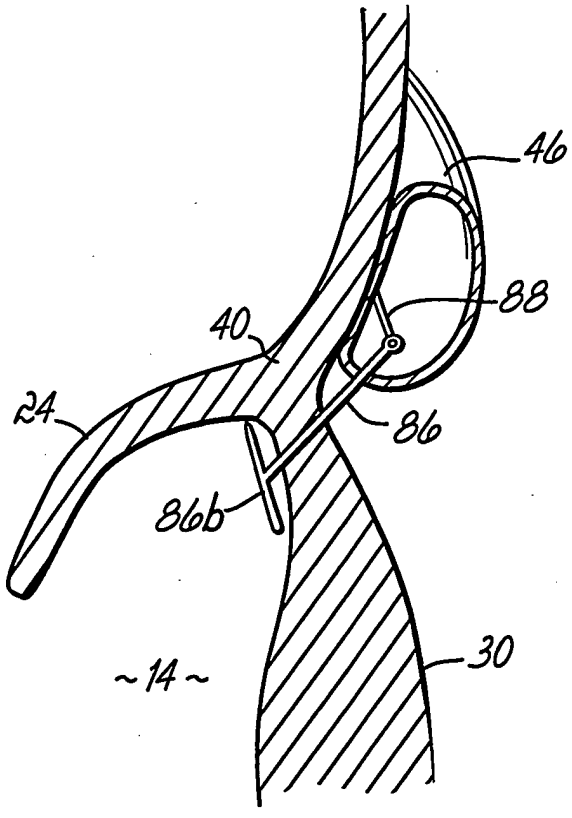


FIG. 7C

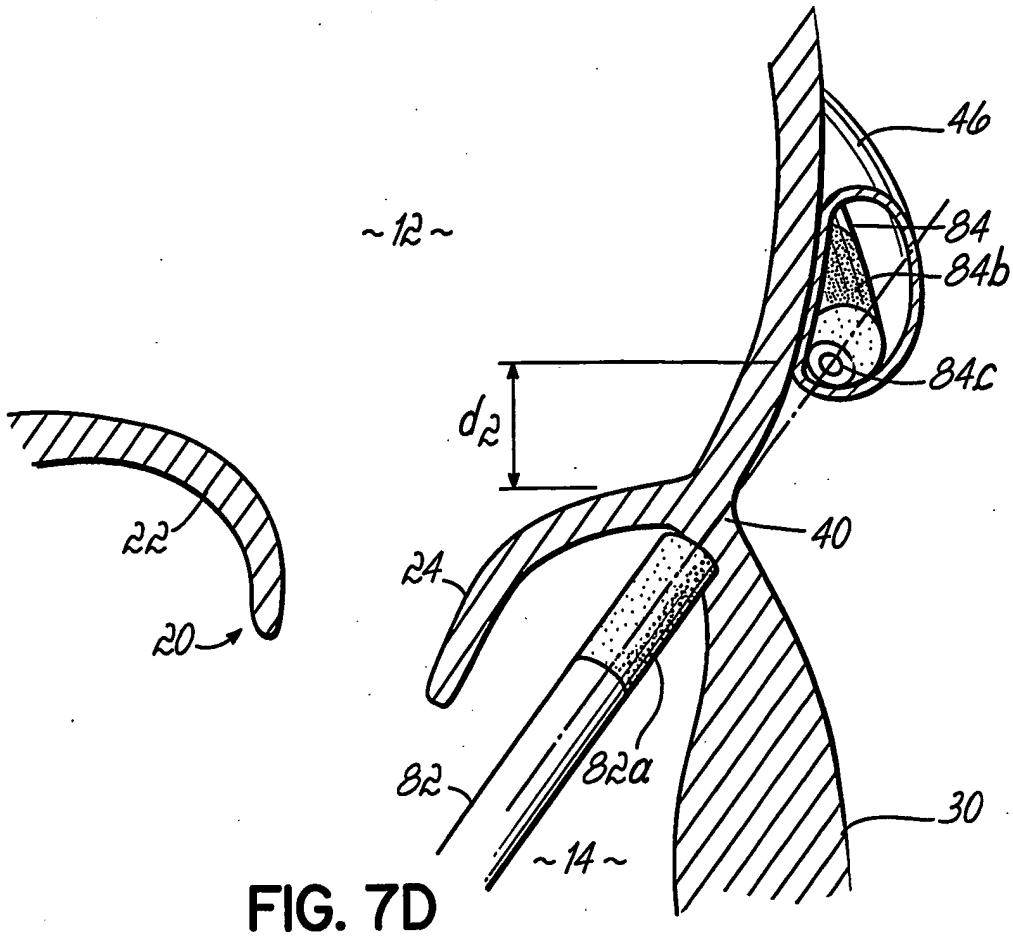


FIG. 7D

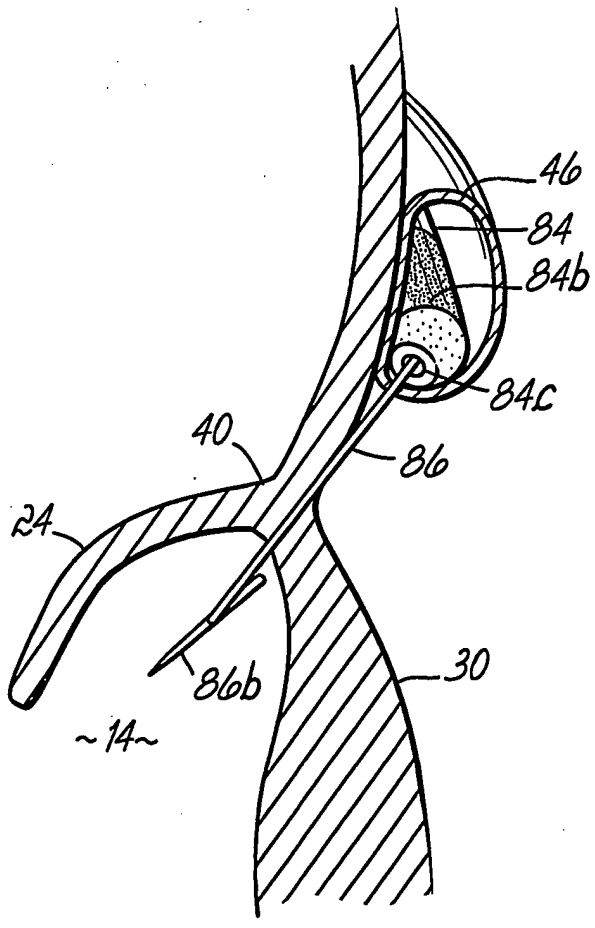


FIG. 7E

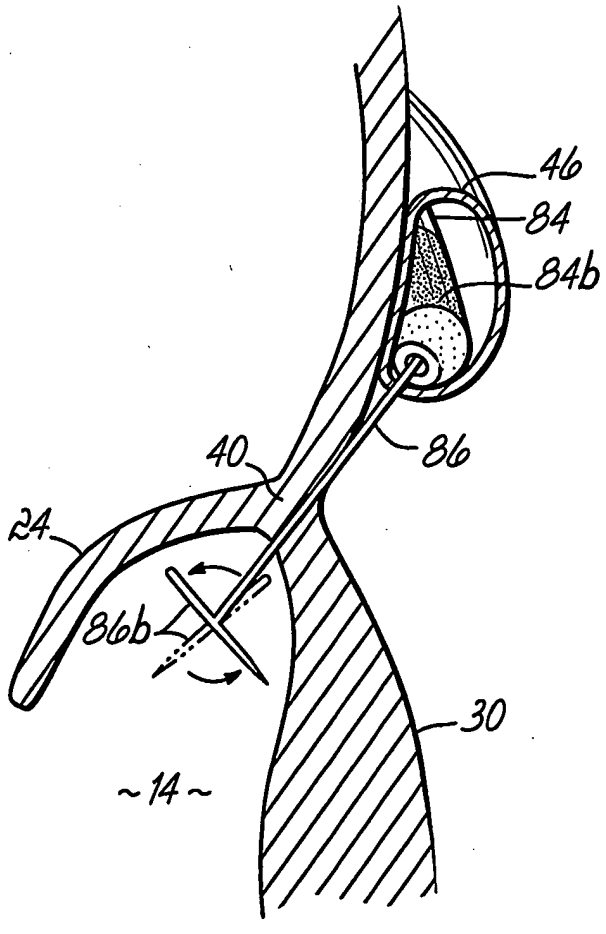


FIG. 7F

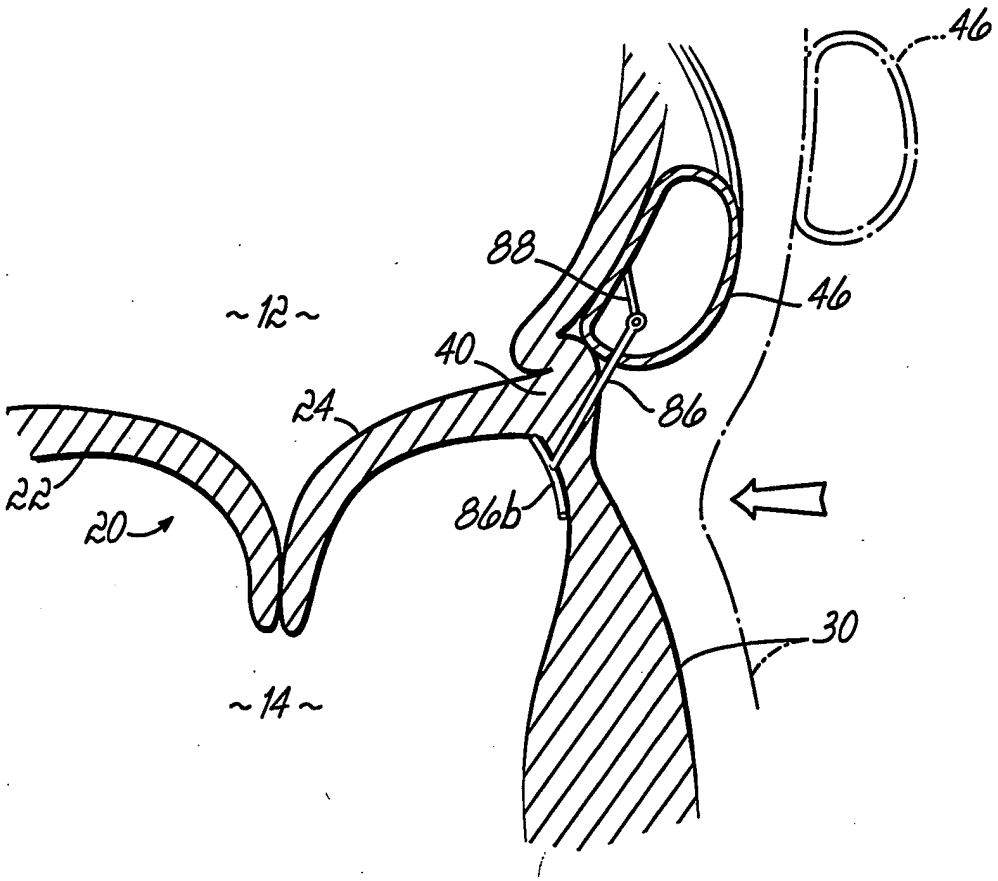


FIG. 7G

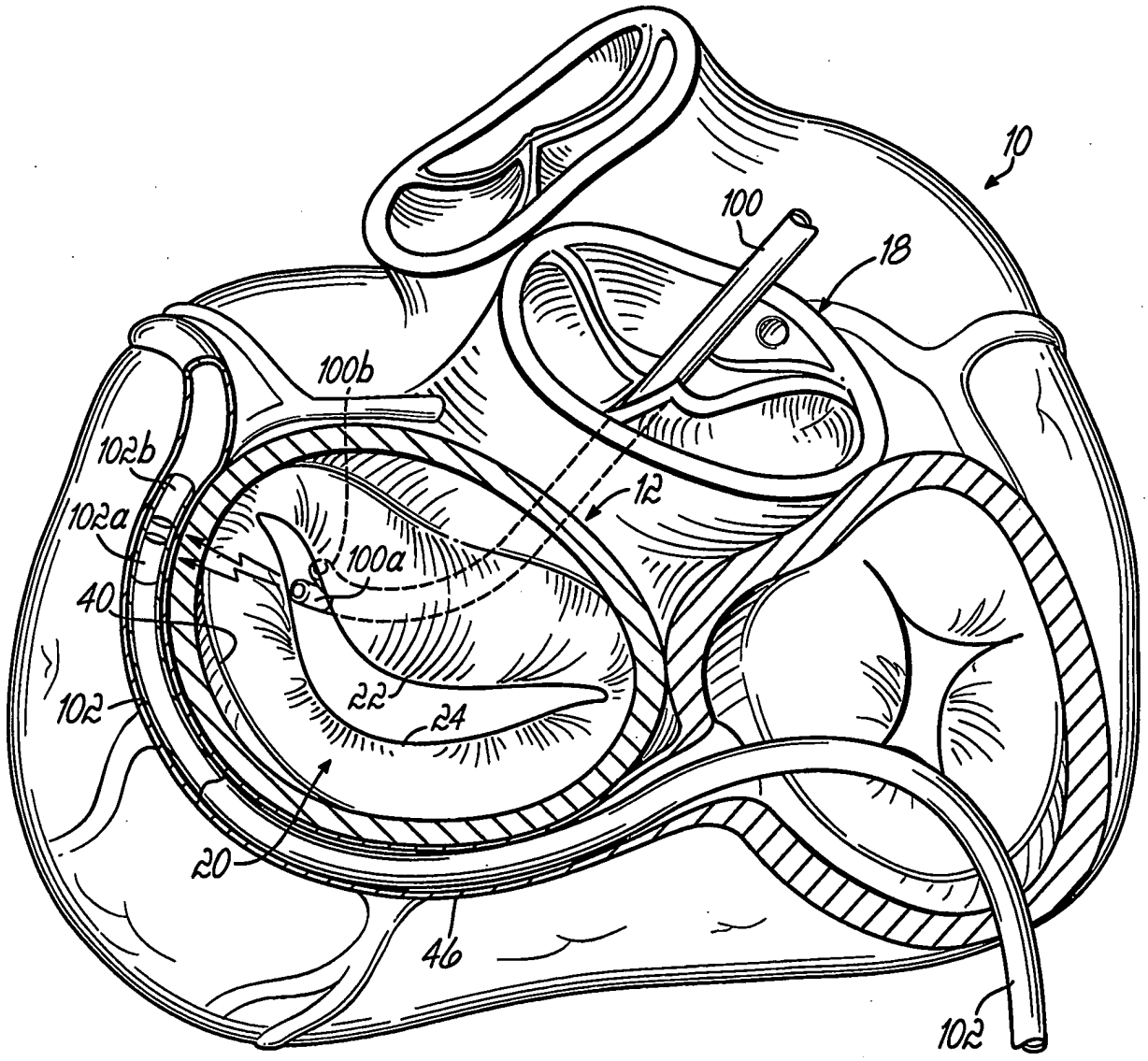


FIG. 8A

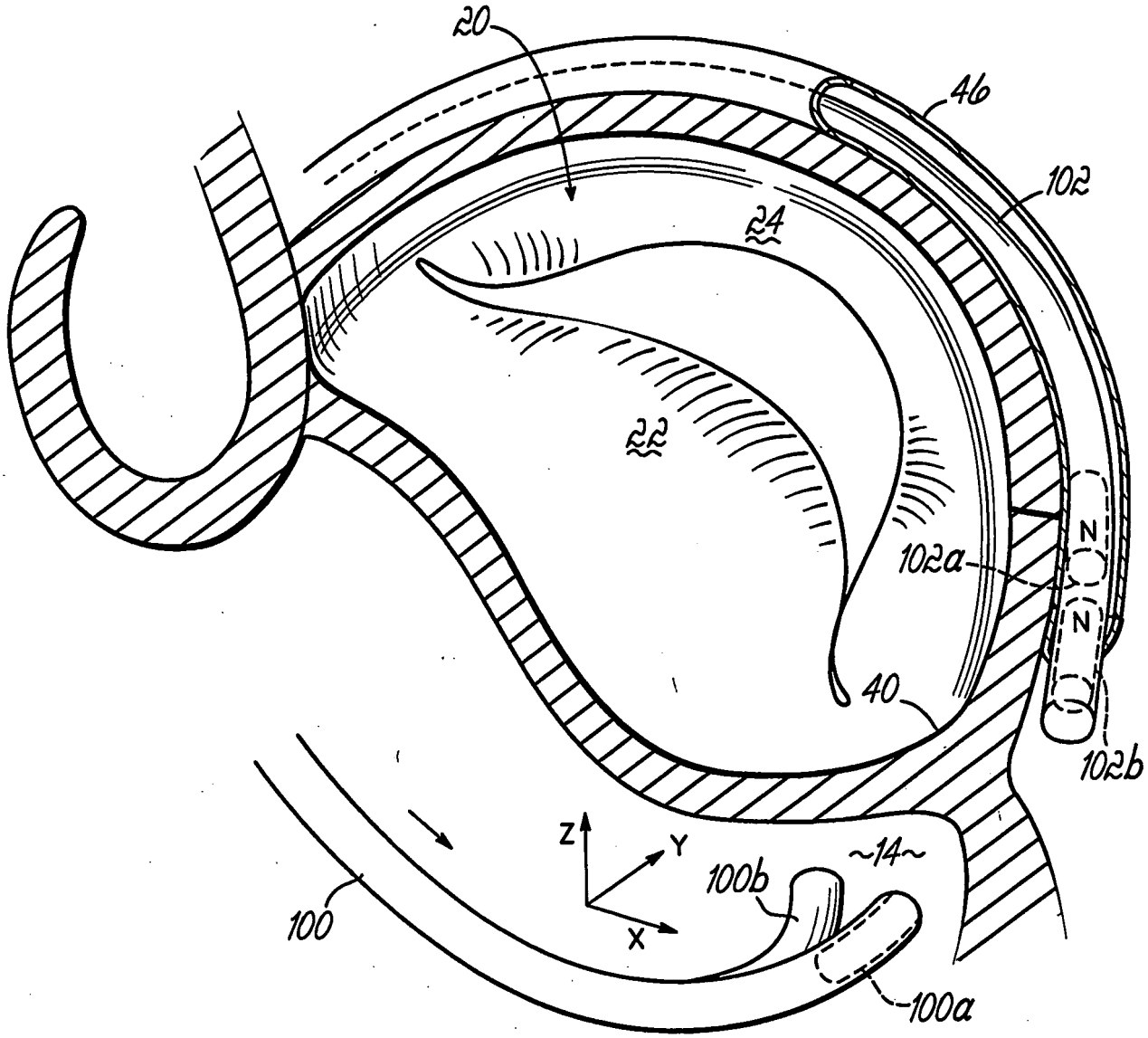

20
46
102
24
22
102a
N
N
40
102b
Z
Y
X
100b
14
100
100a

FIG. 8B

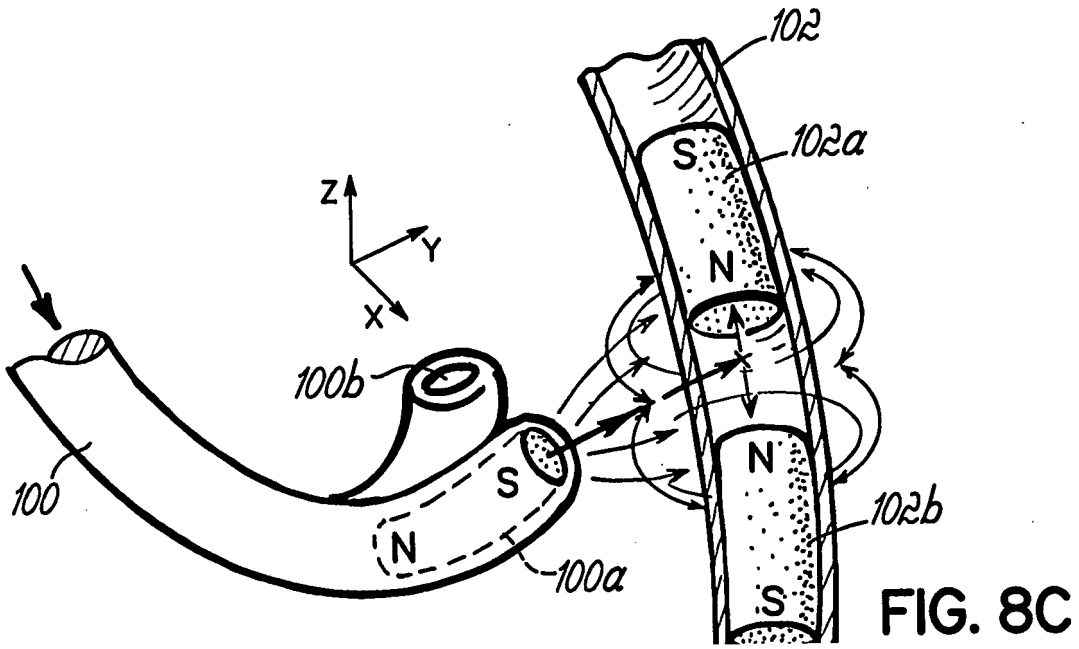

102
S
102a
Z
Y
X
N
100b
N
S
102b
100
S
N
100a

FIG. 8C

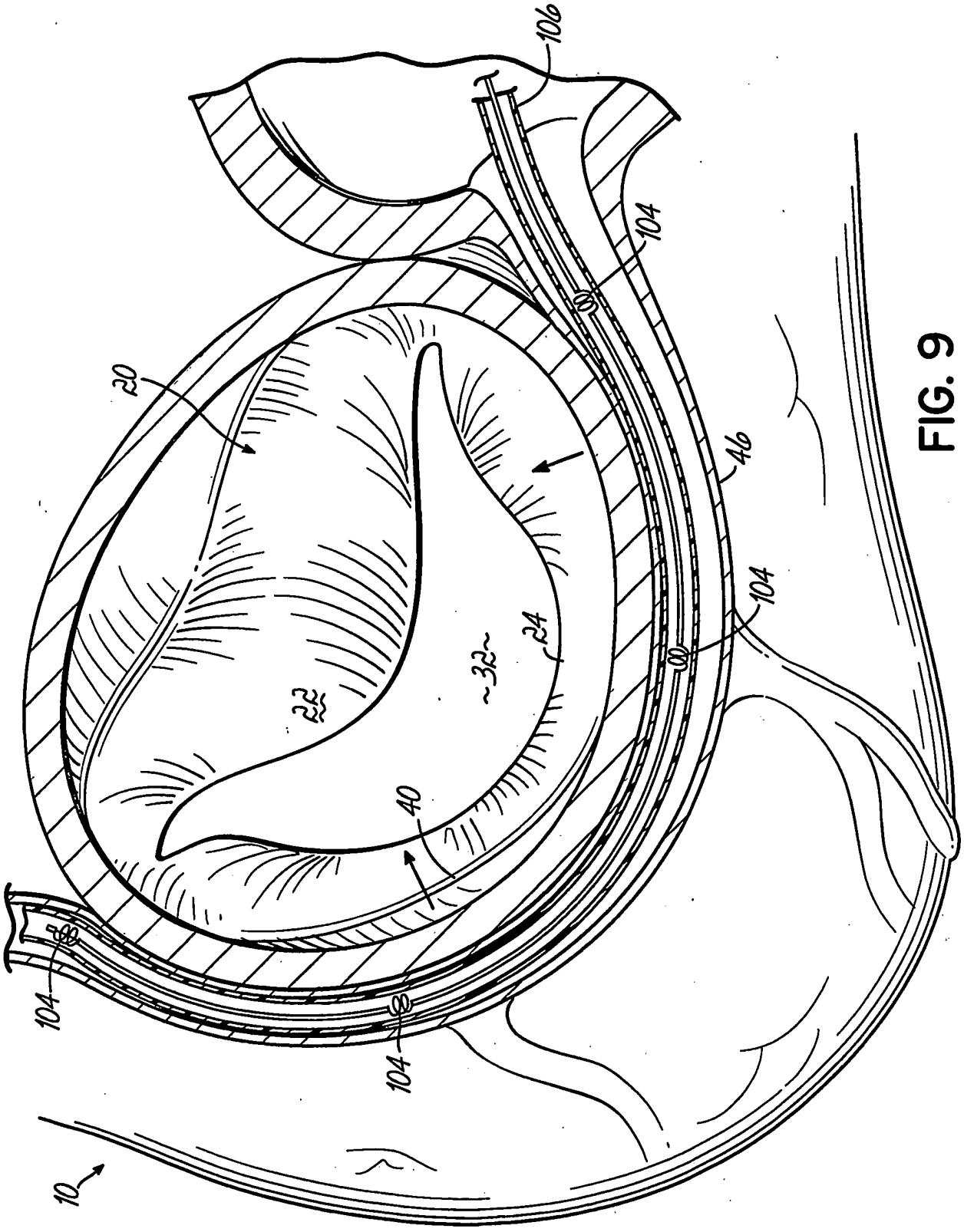


FIG. 9

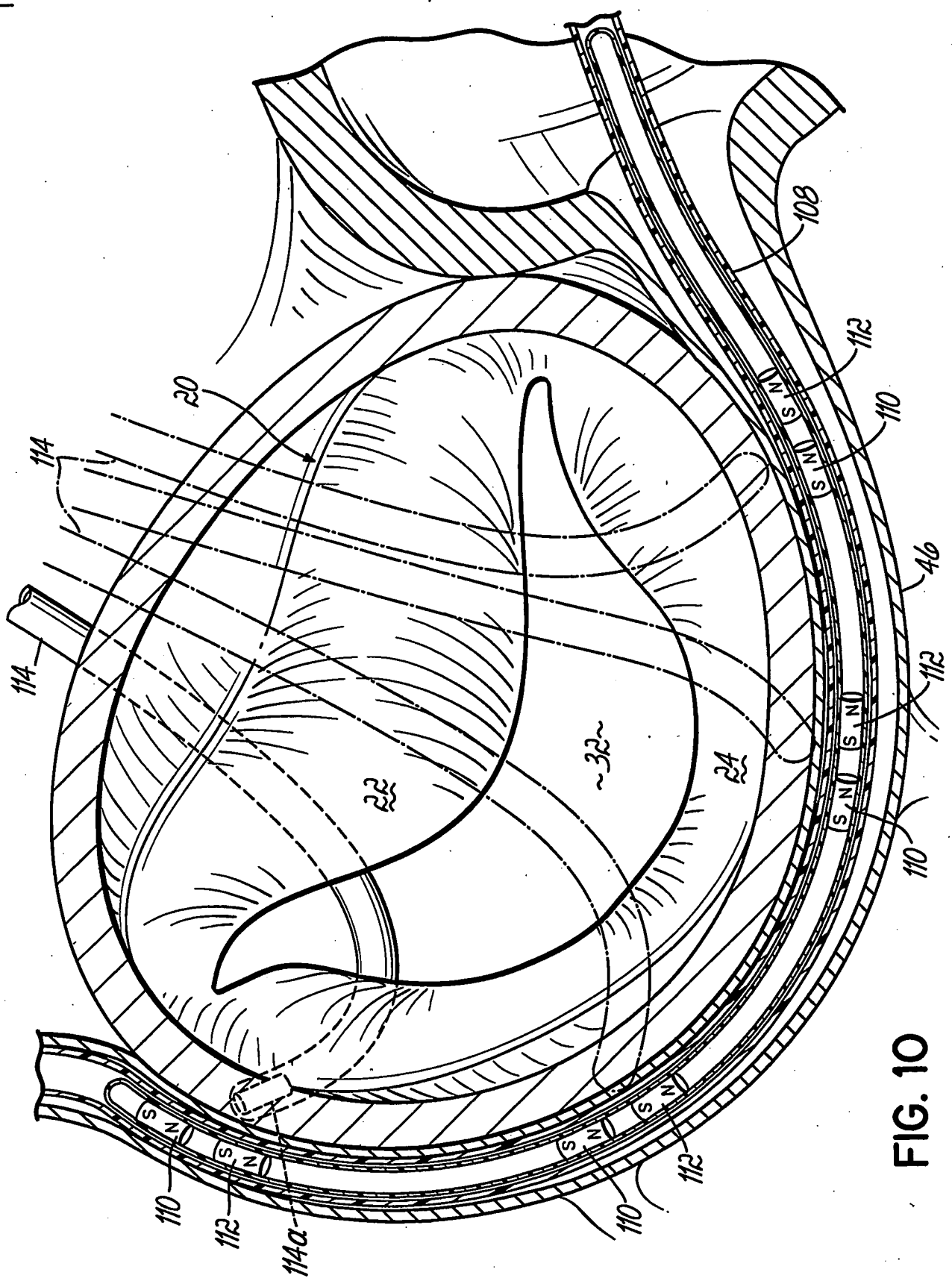


FIG. 10

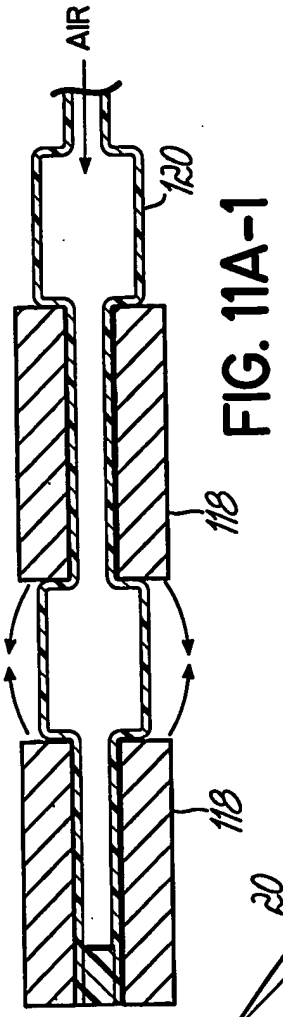


FIG. 11A-1

FIG. 11A

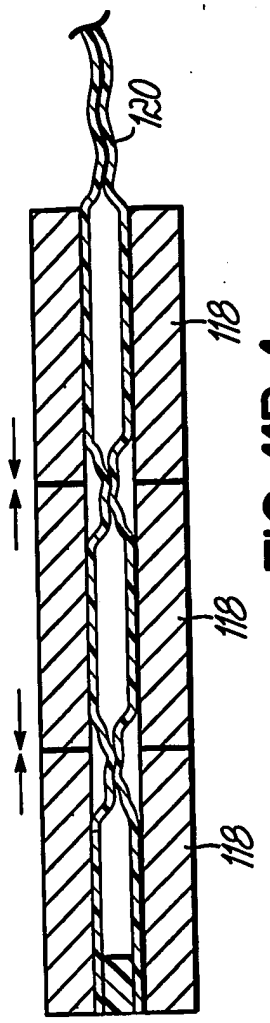


FIG. 11B-1

FIG. 11B

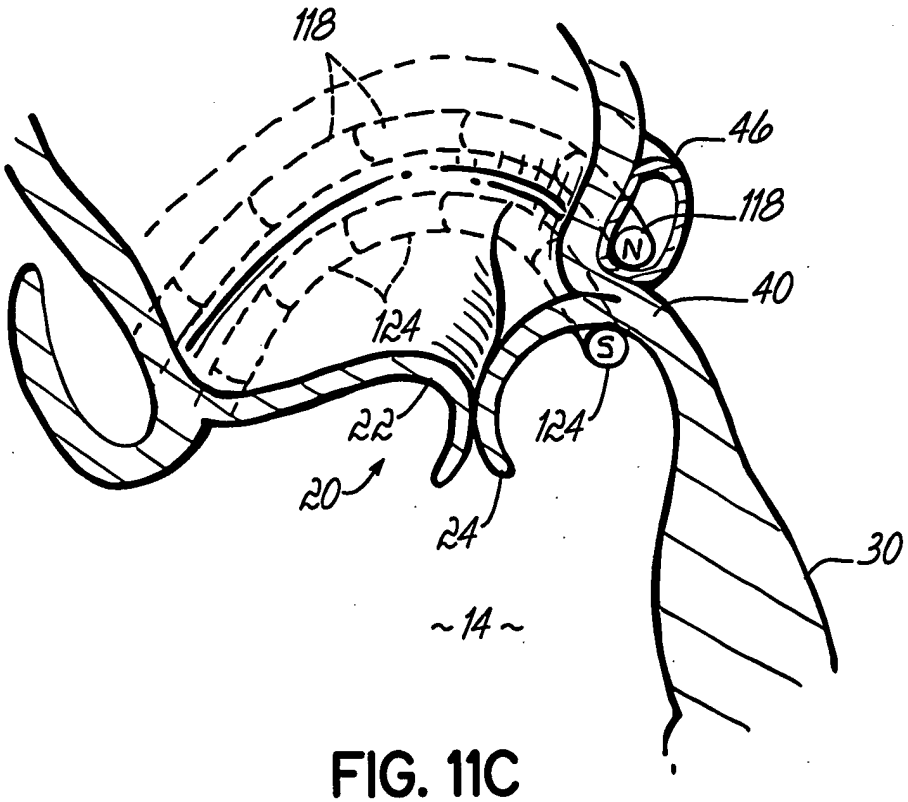


FIG. 11C

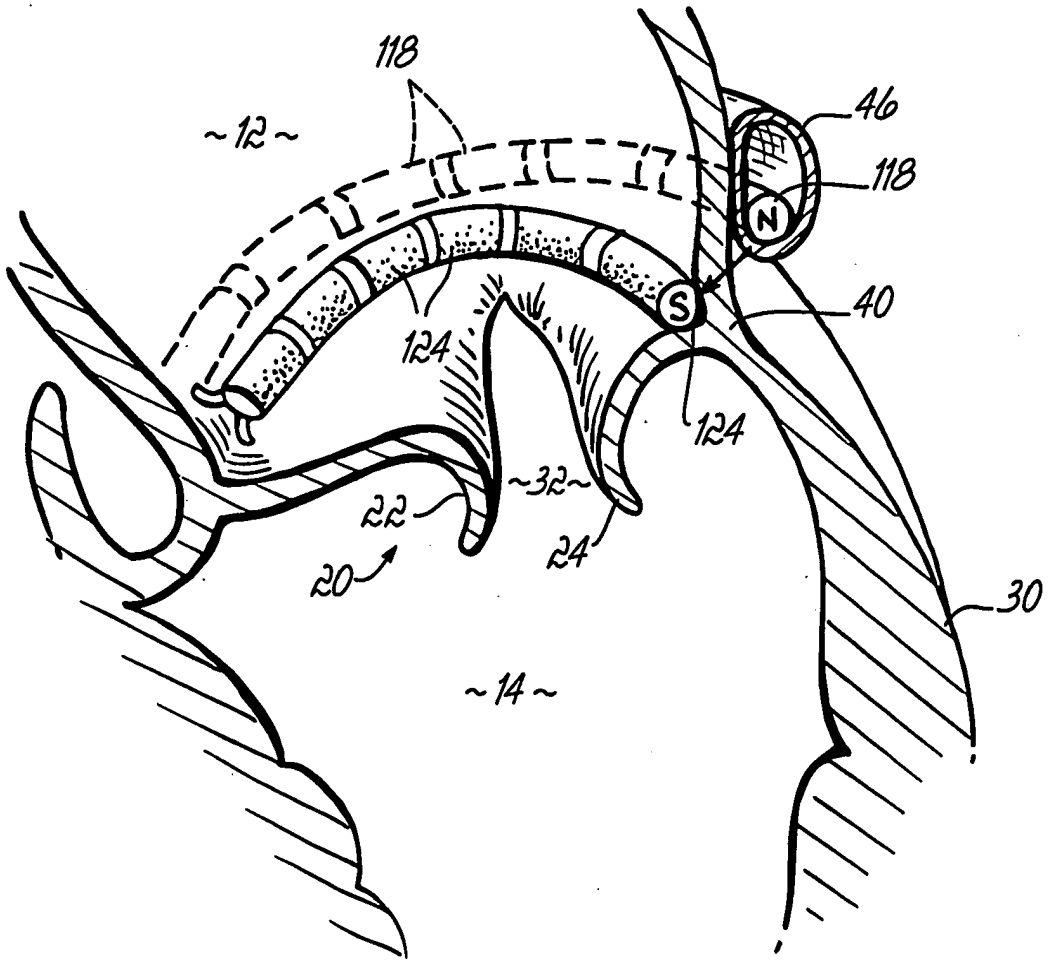


FIG. 12A

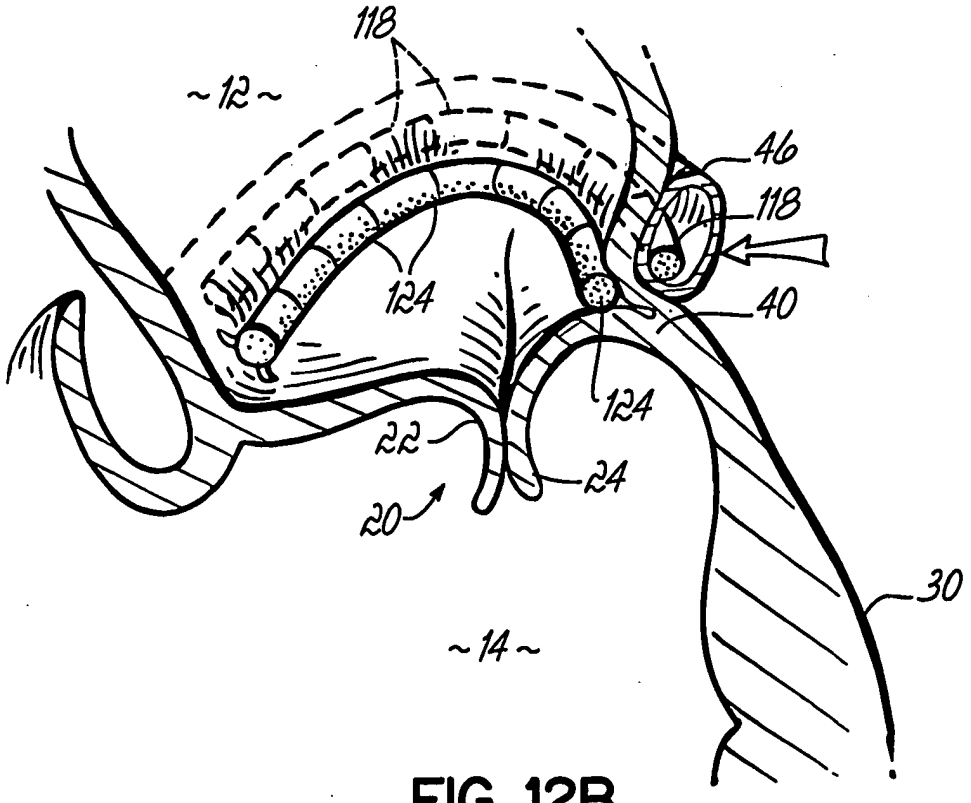


FIG. 12B

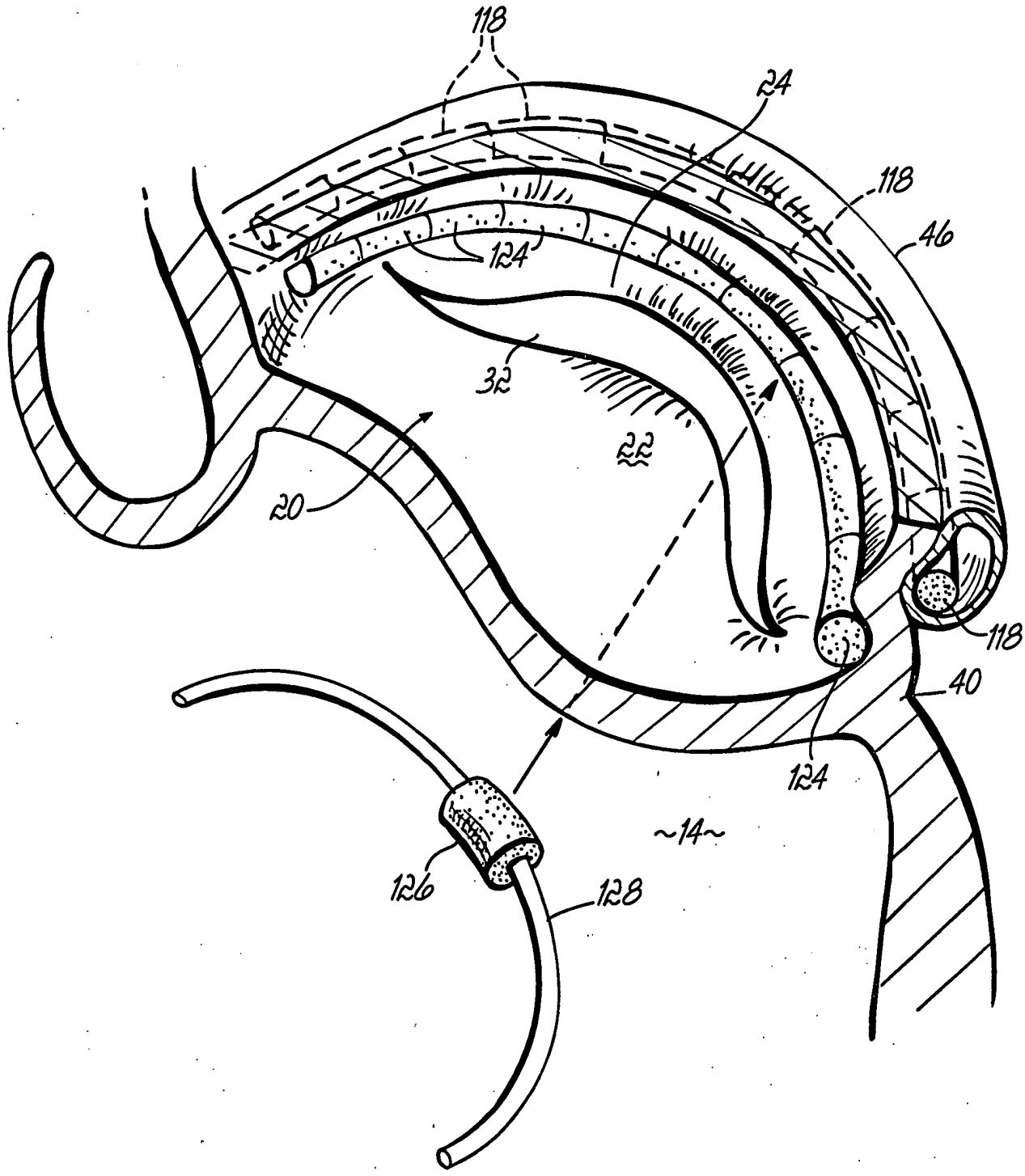


FIG. 13A

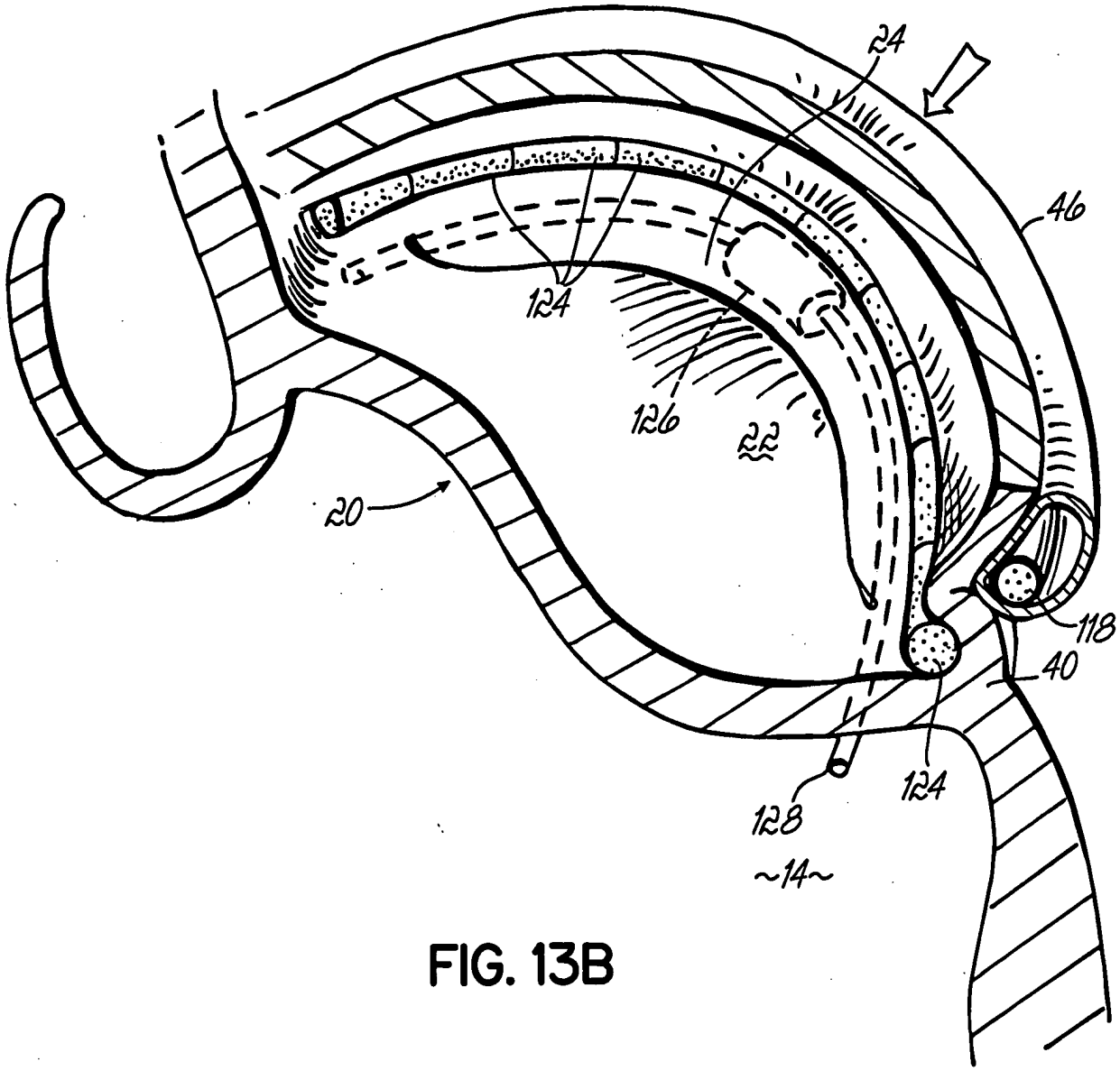


FIG. 13B

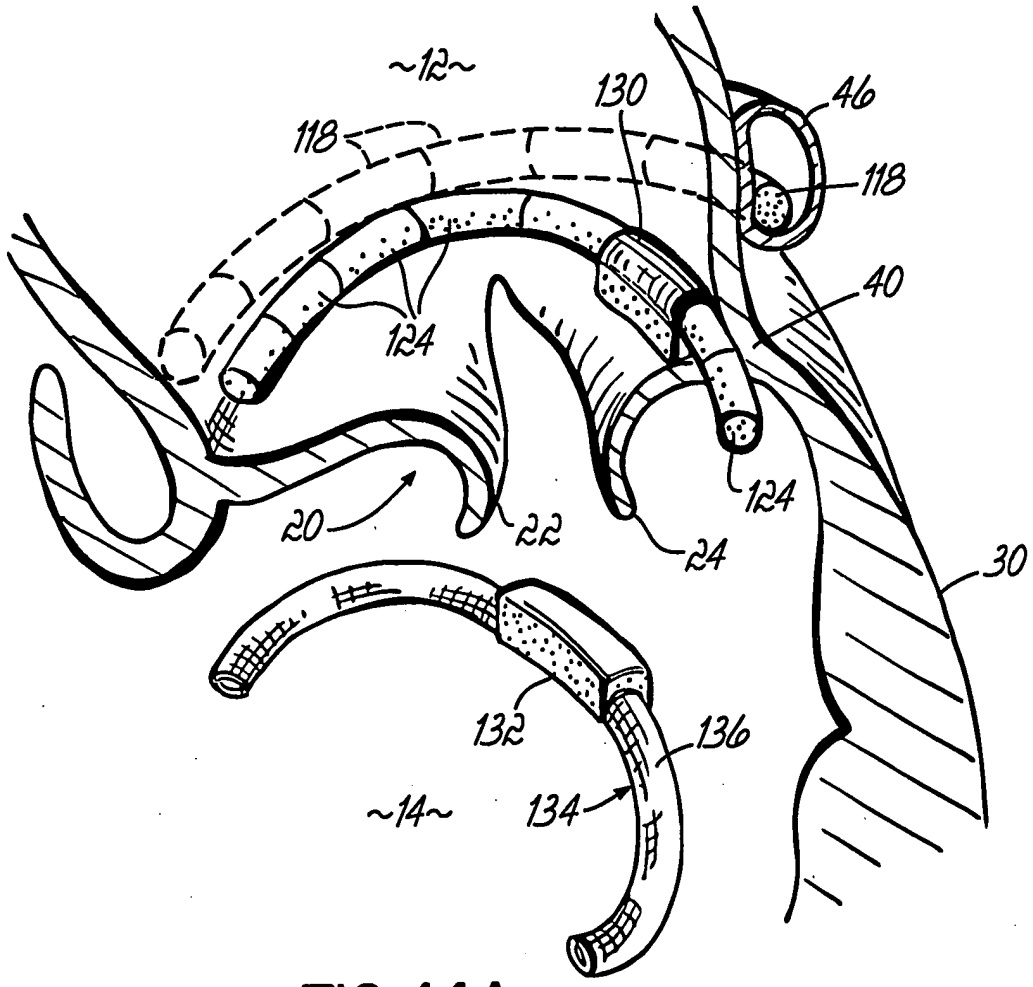


FIG. 14A

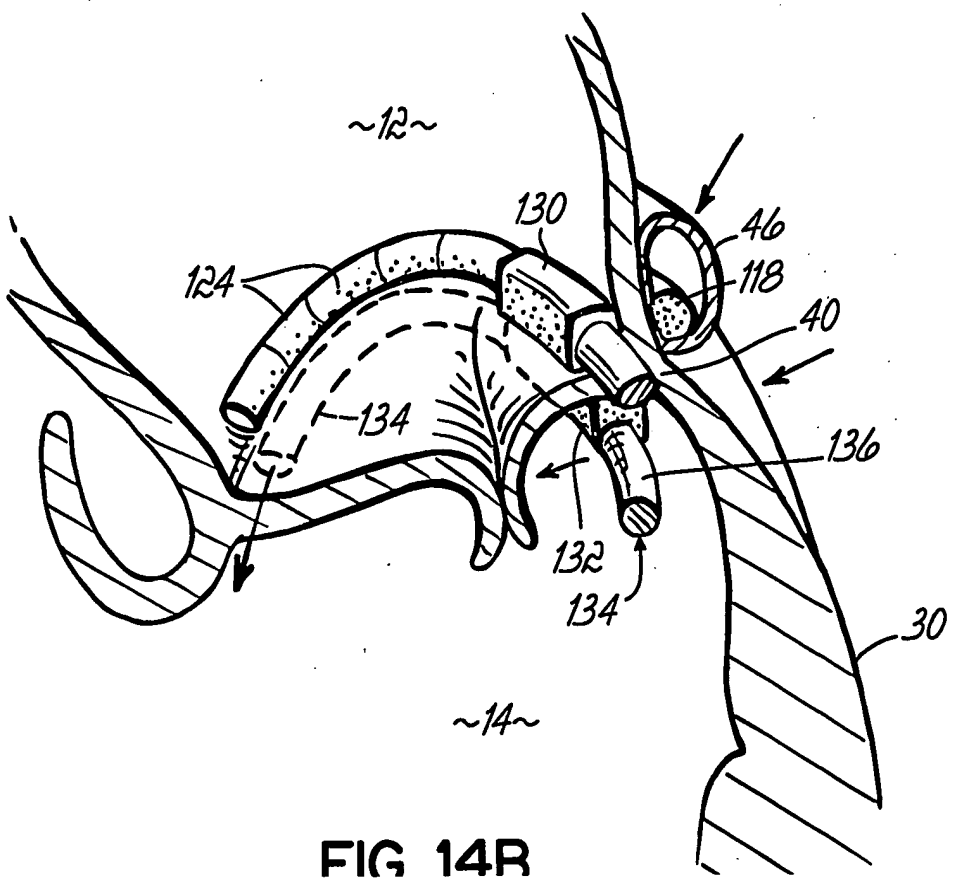


FIG. 14B

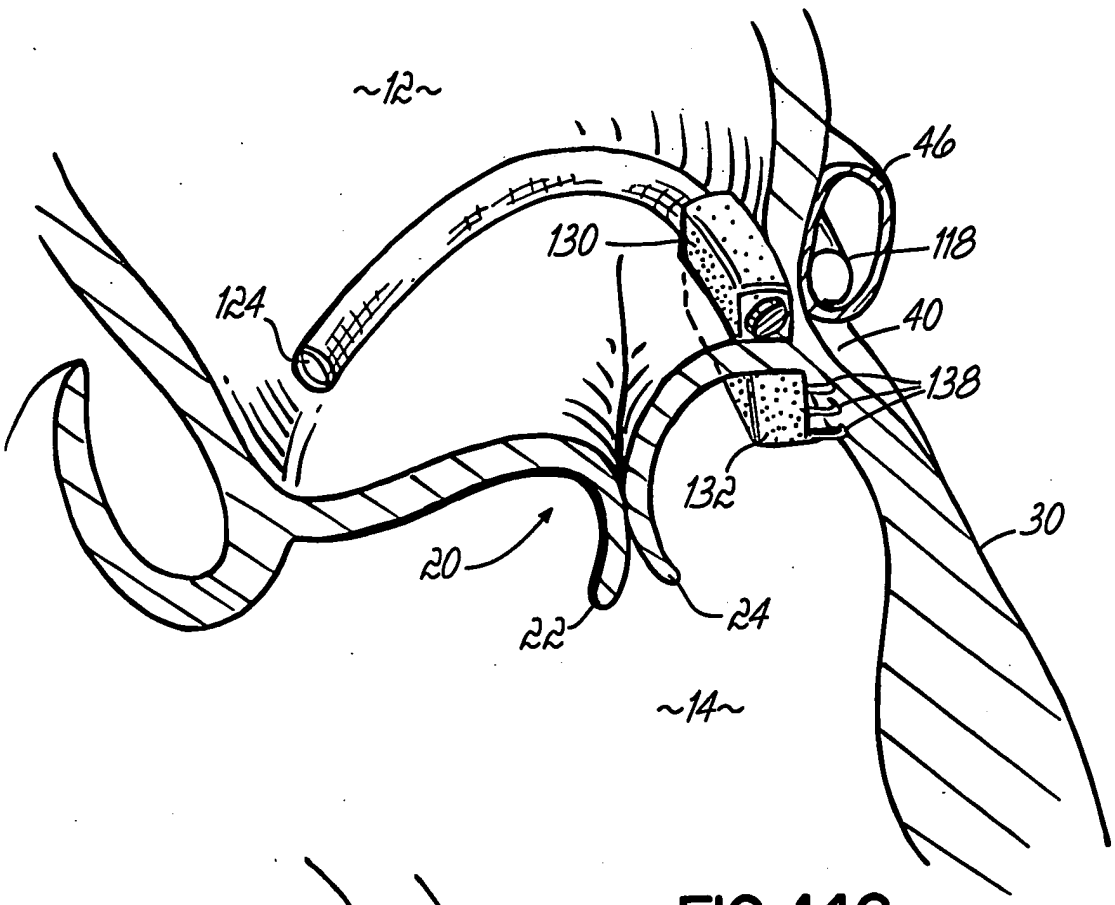


FIG. 14C

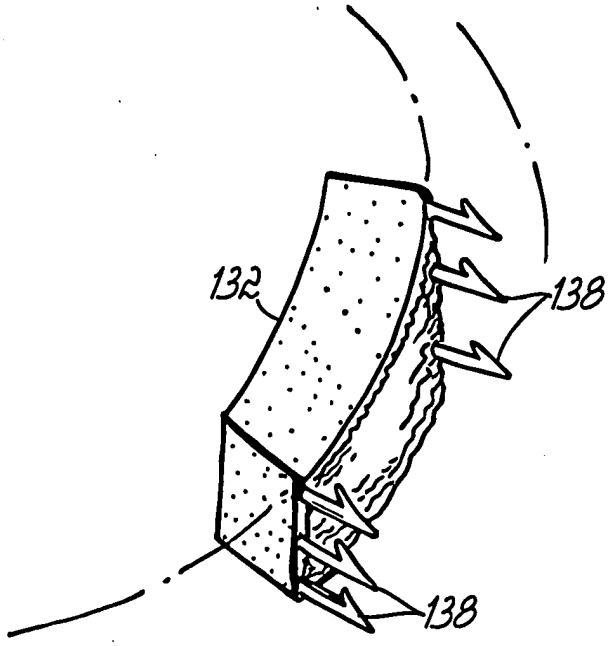


FIG. 14D

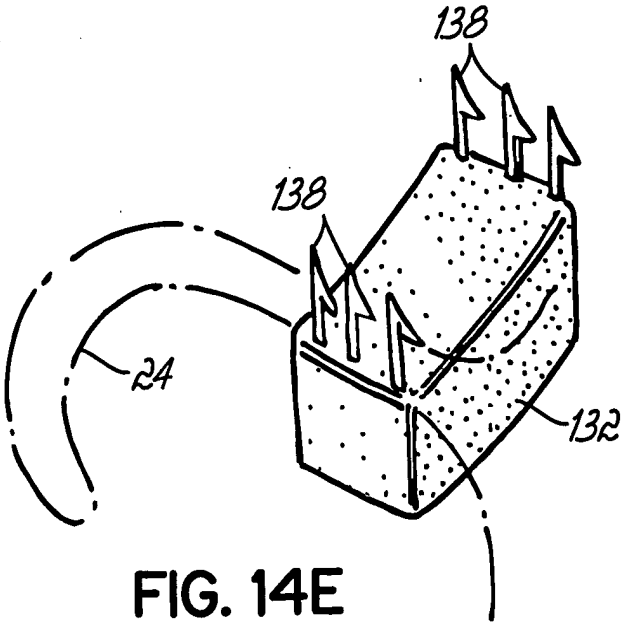


FIG. 14E

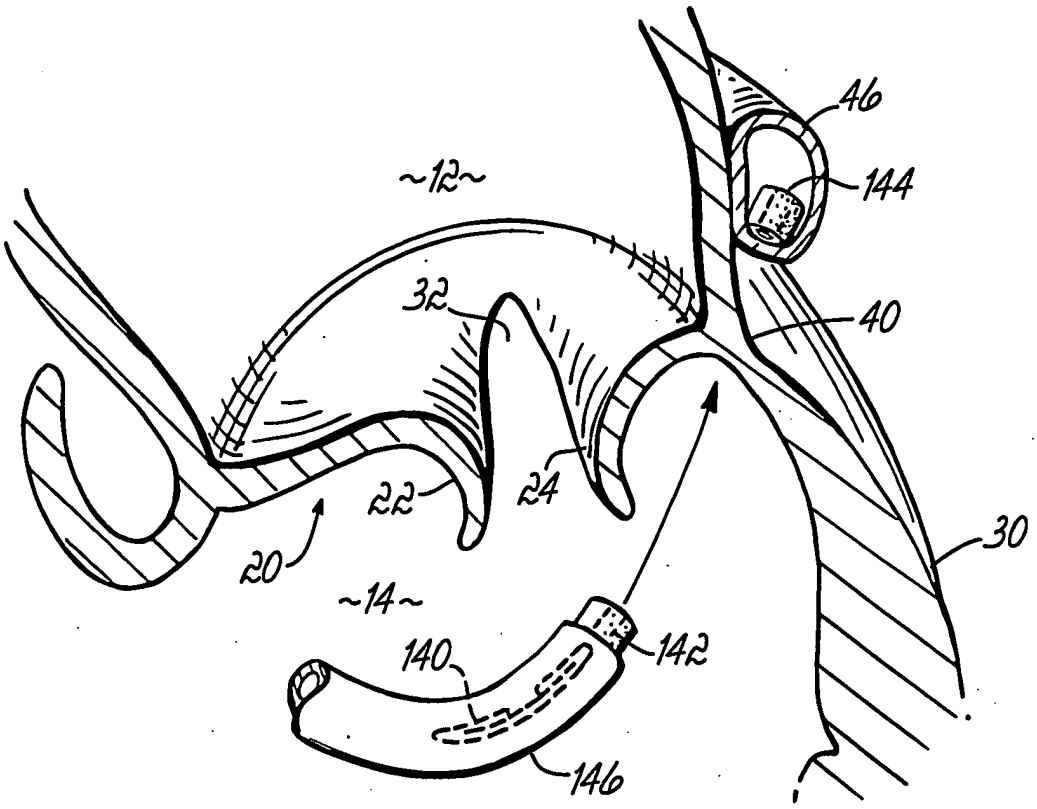


FIG. 15A

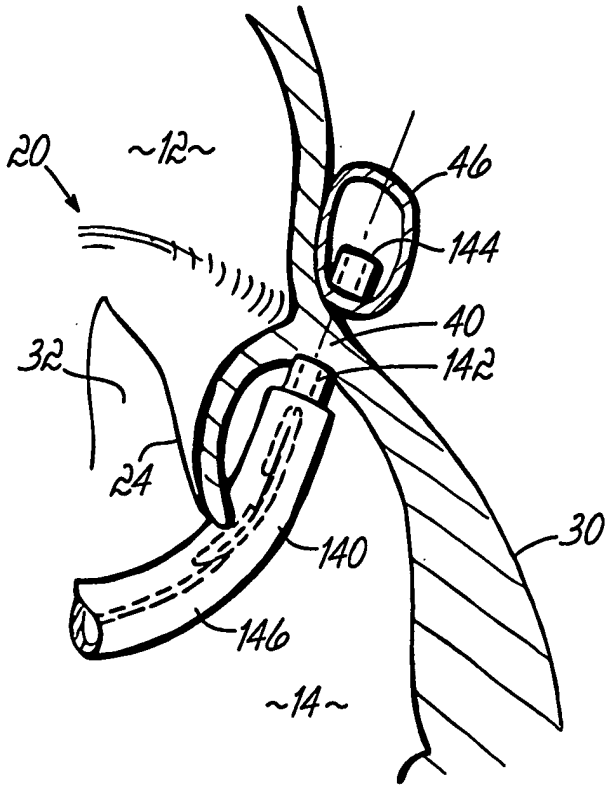


FIG. 15B

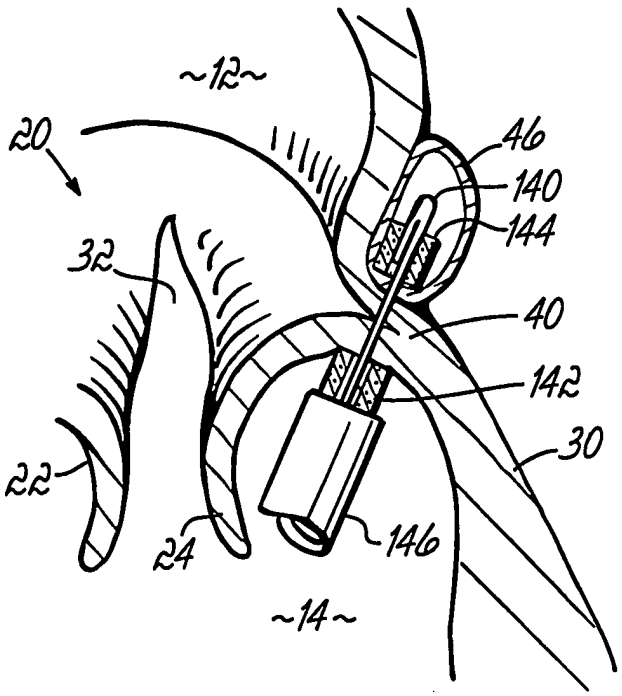


FIG. 15C

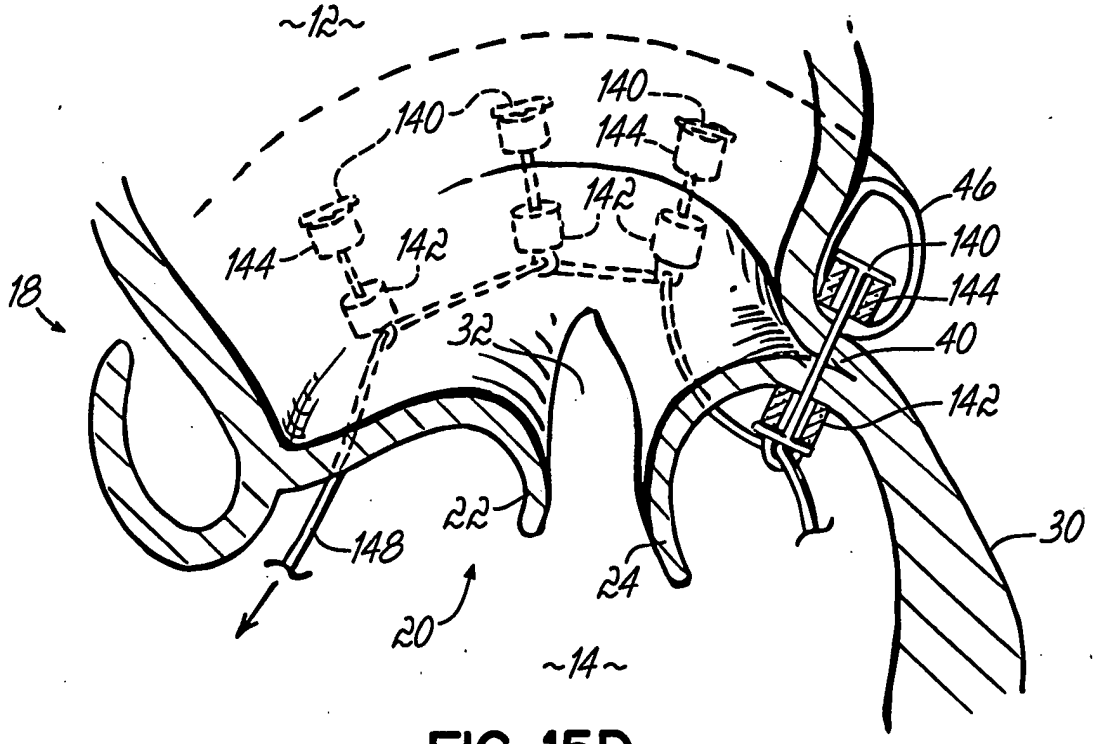


FIG. 15D

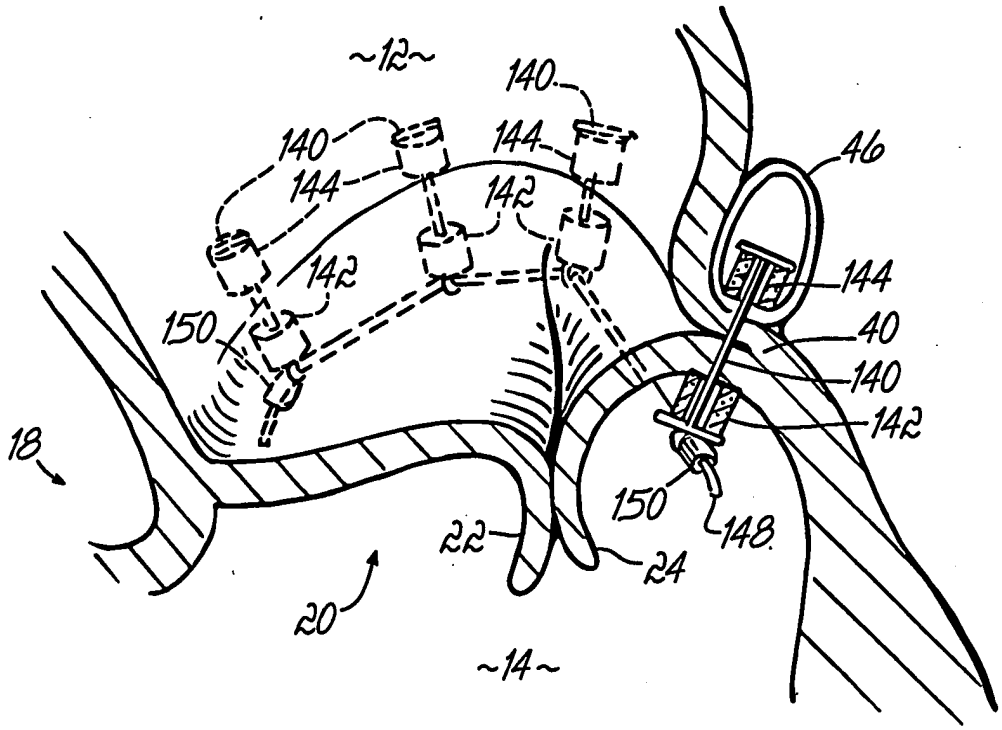


FIG. 15E

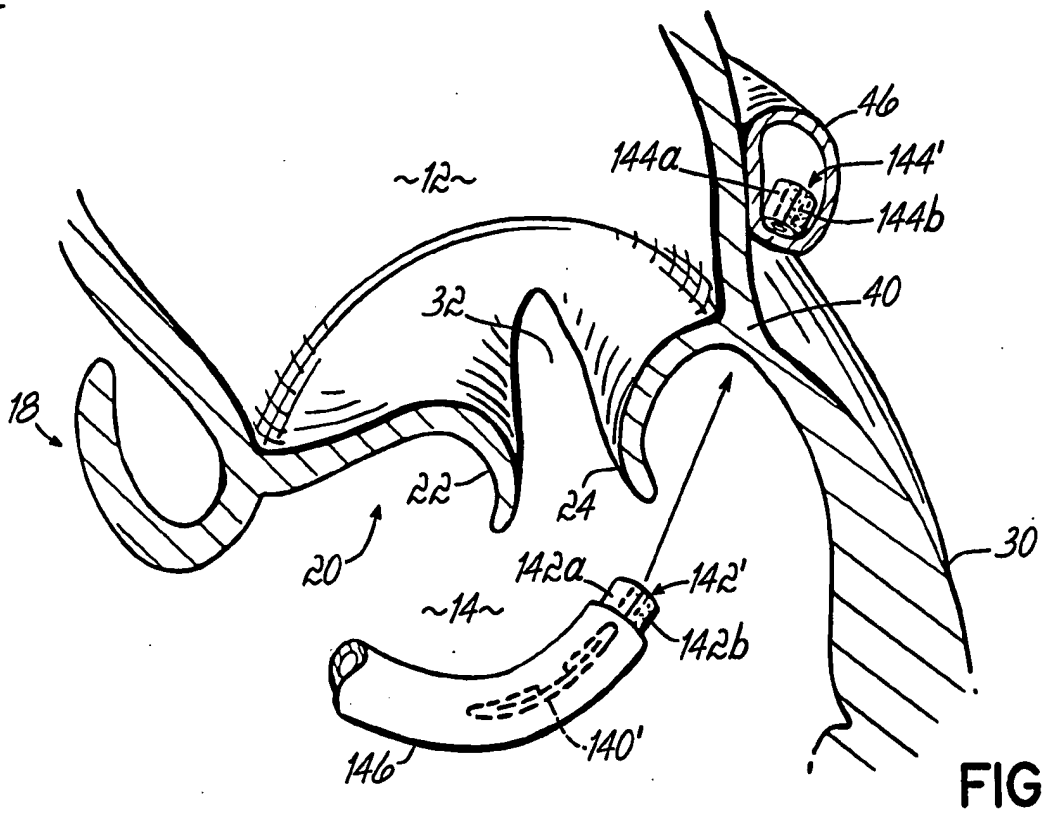


FIG. 16A

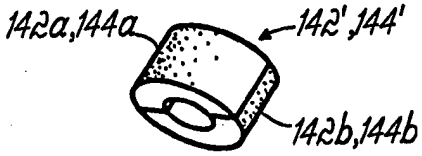


FIG. 16A-1

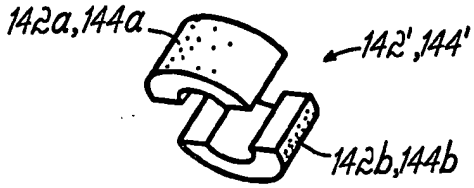


FIG. 16A-2

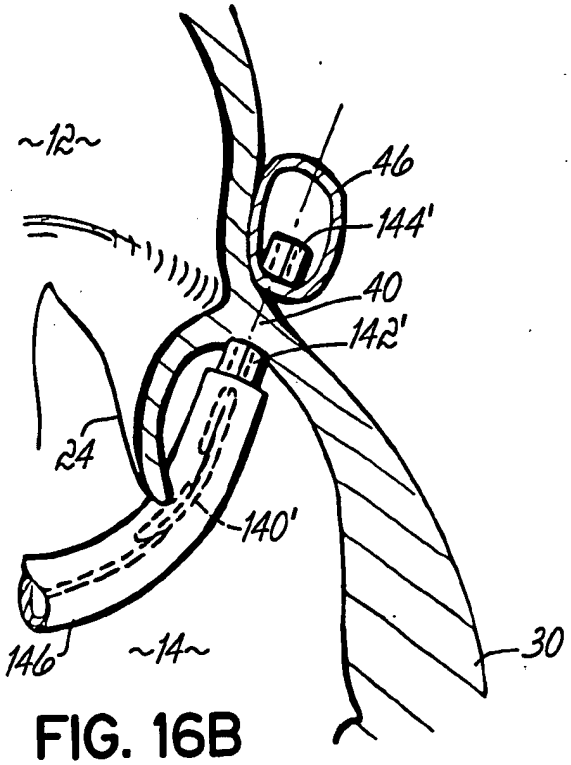


FIG. 16B

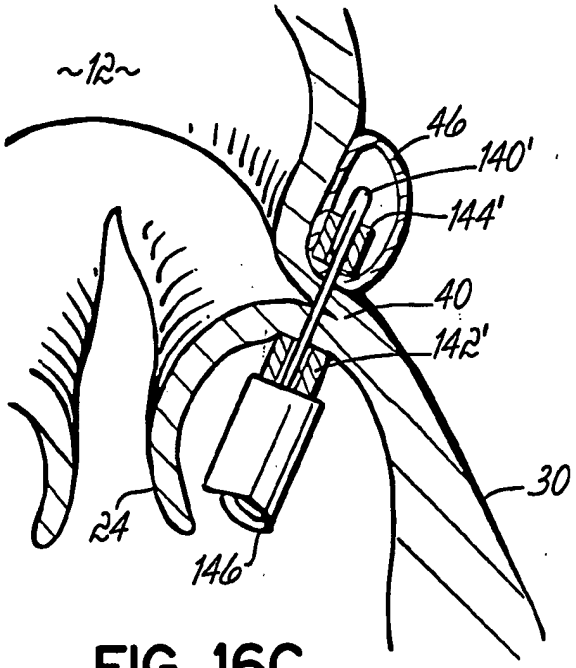


FIG. 16C

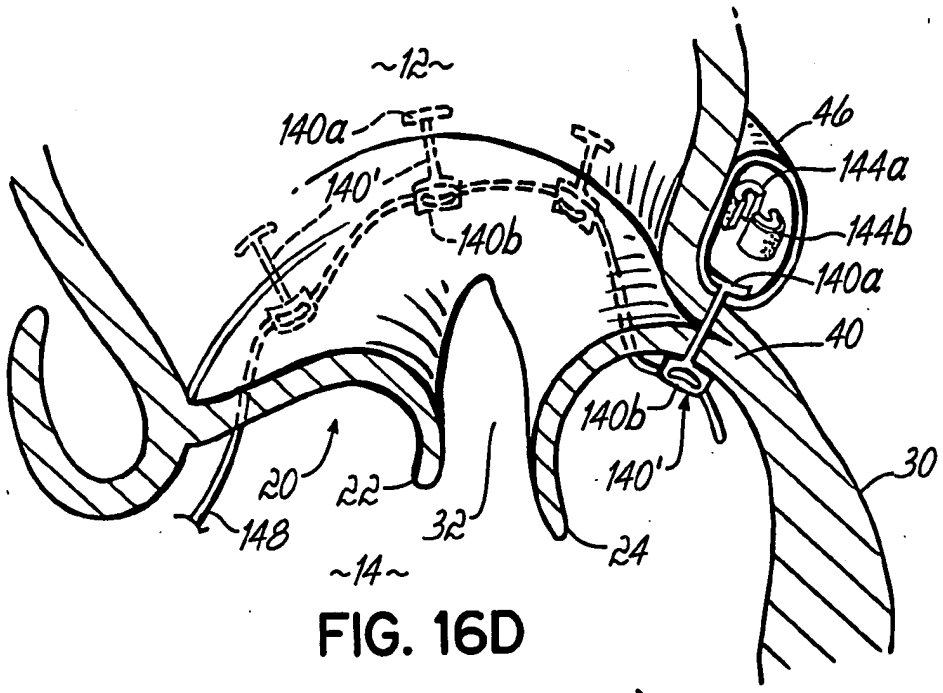


FIG. 16D

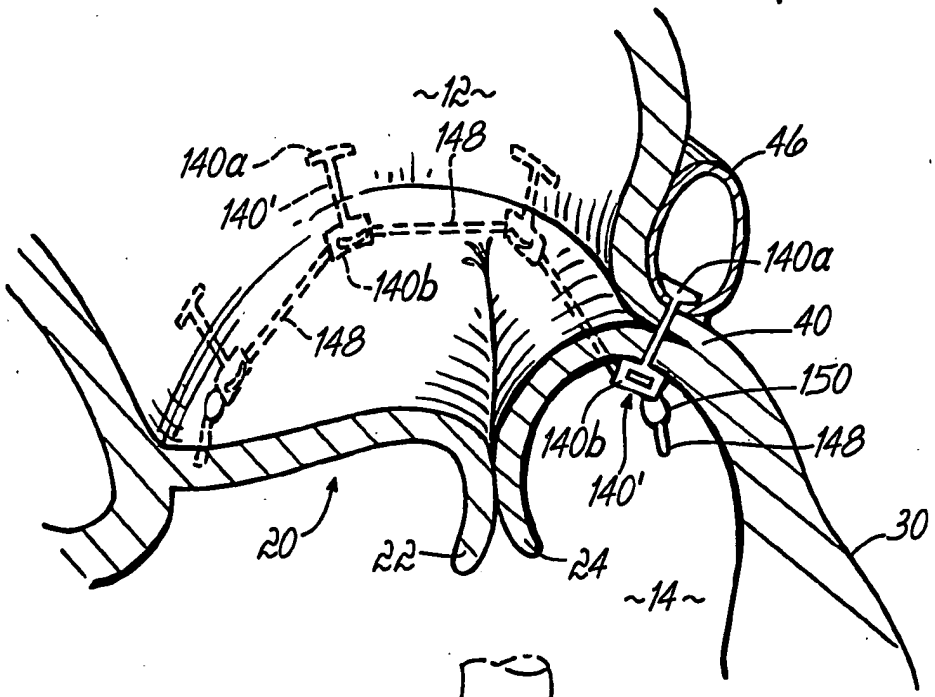


FIG. 16E

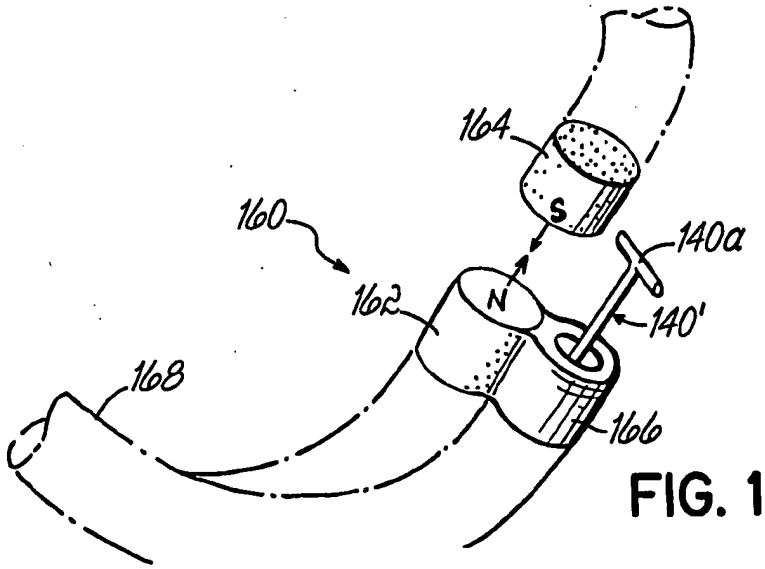


FIG. 17

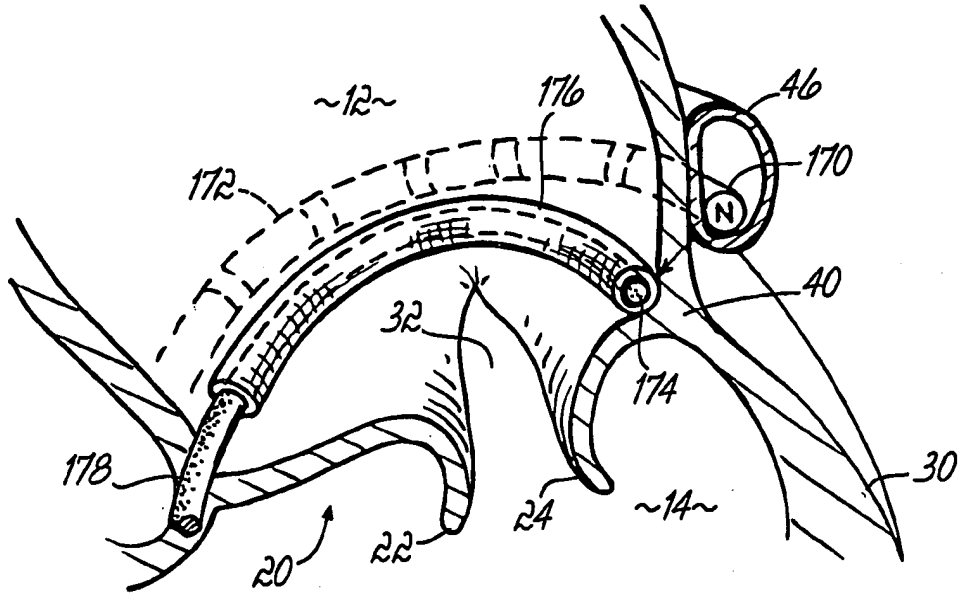


FIG. 18A

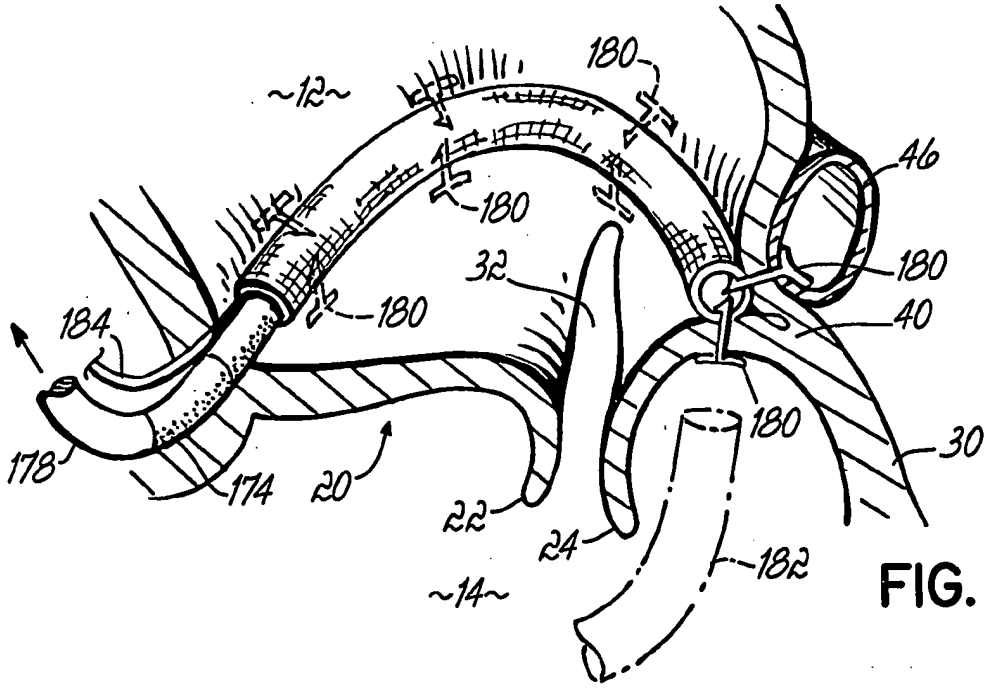


FIG. 18B

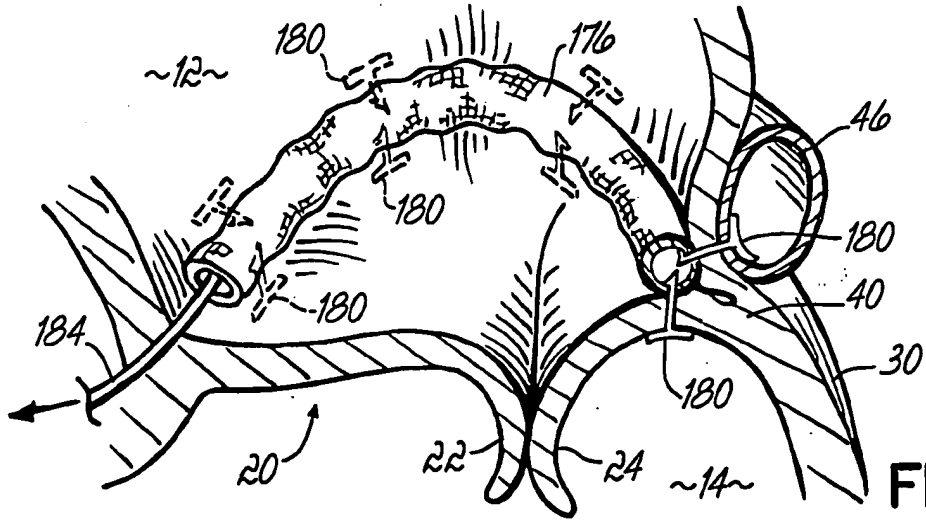


FIG. 18C

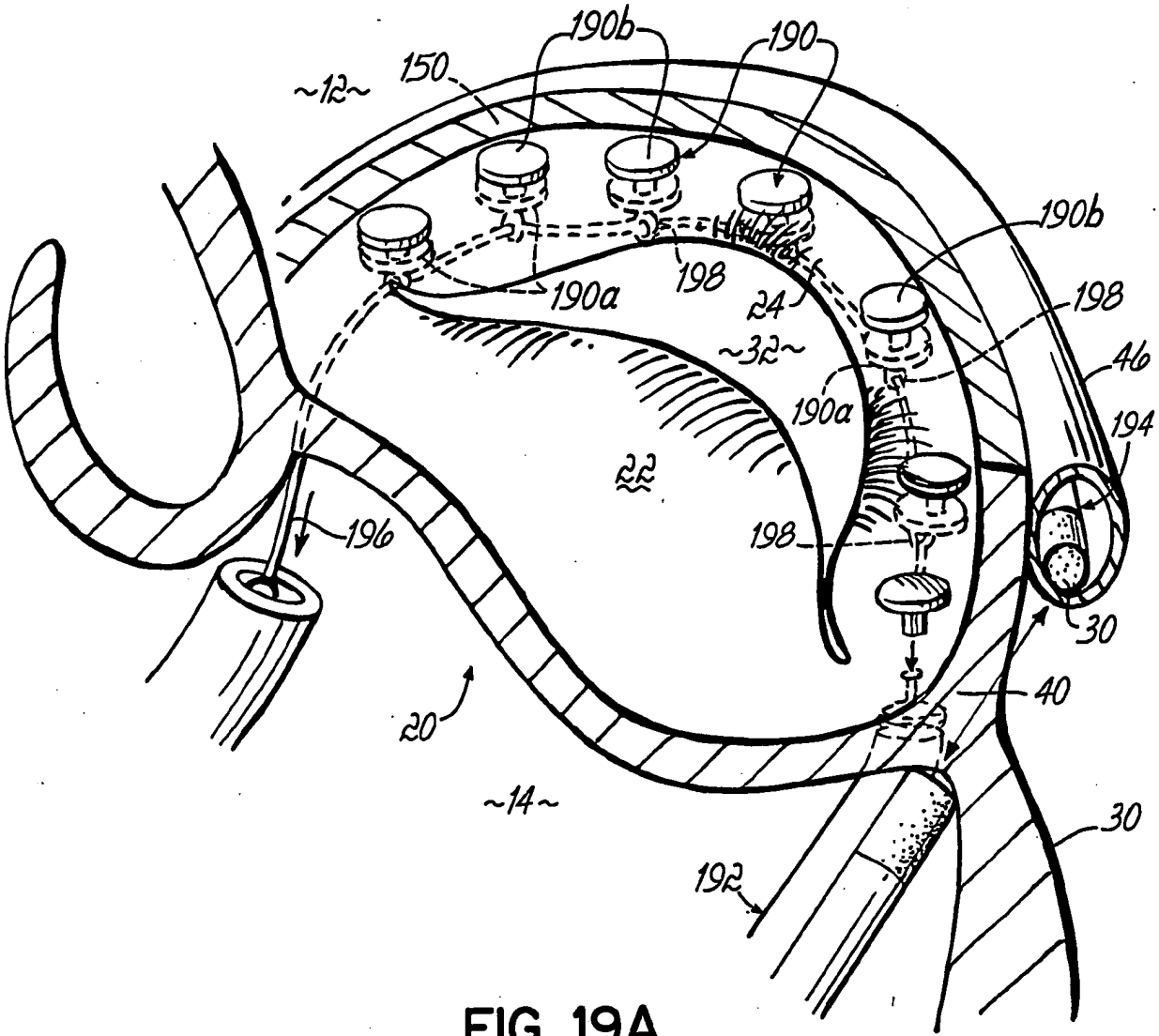


FIG. 19A

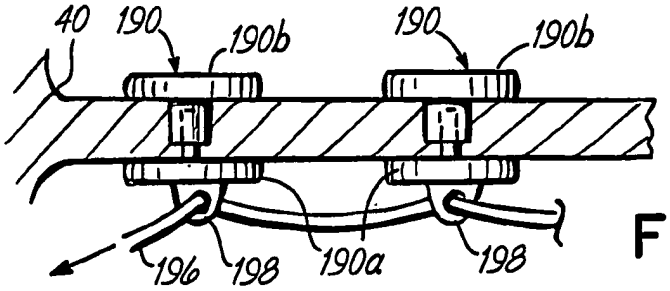


FIG. 19B

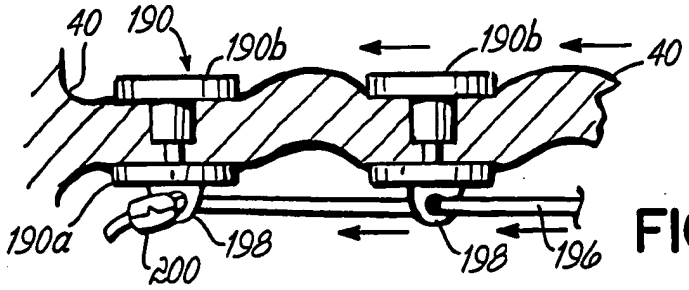


FIG. 19C

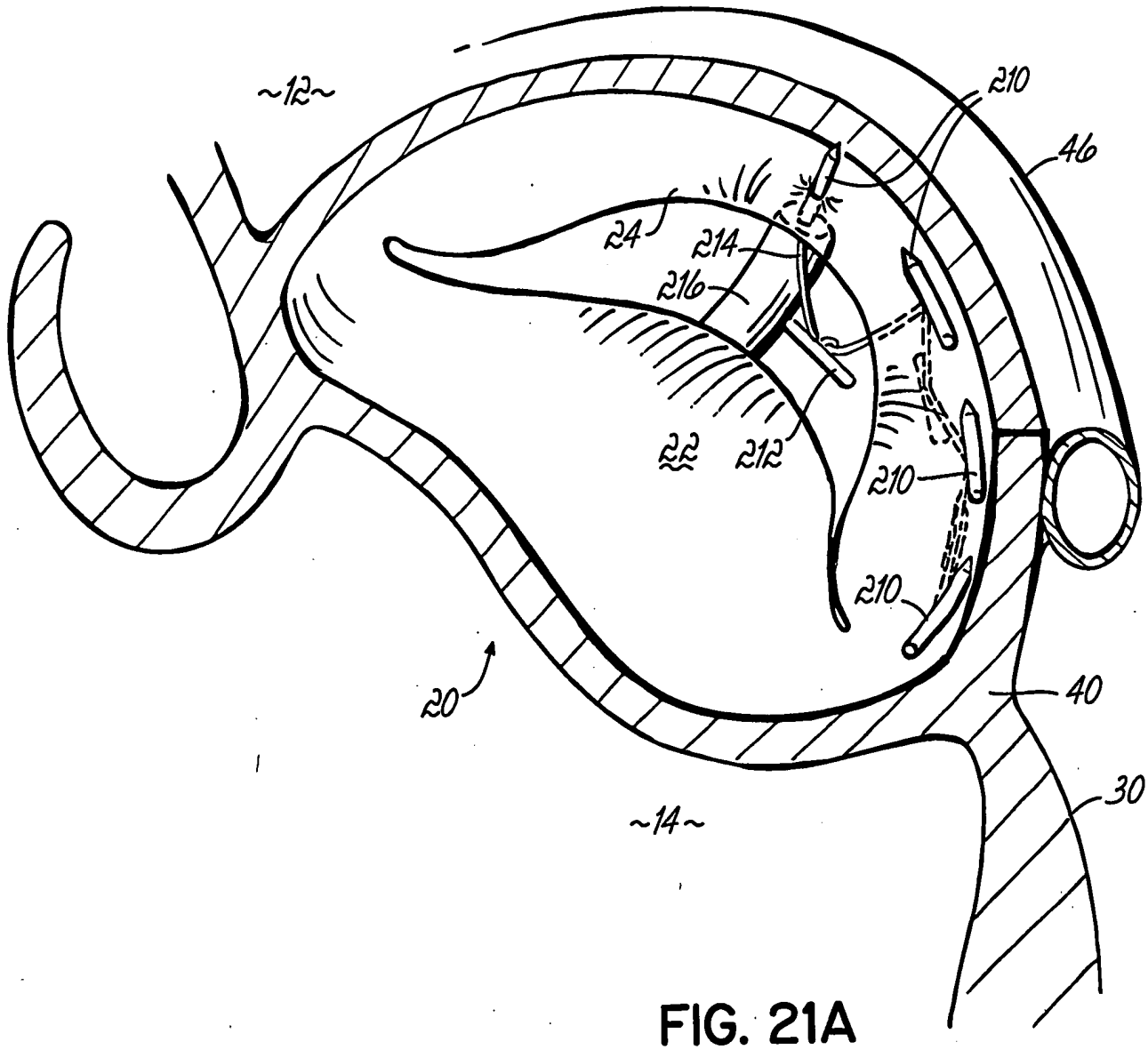


FIG. 21A

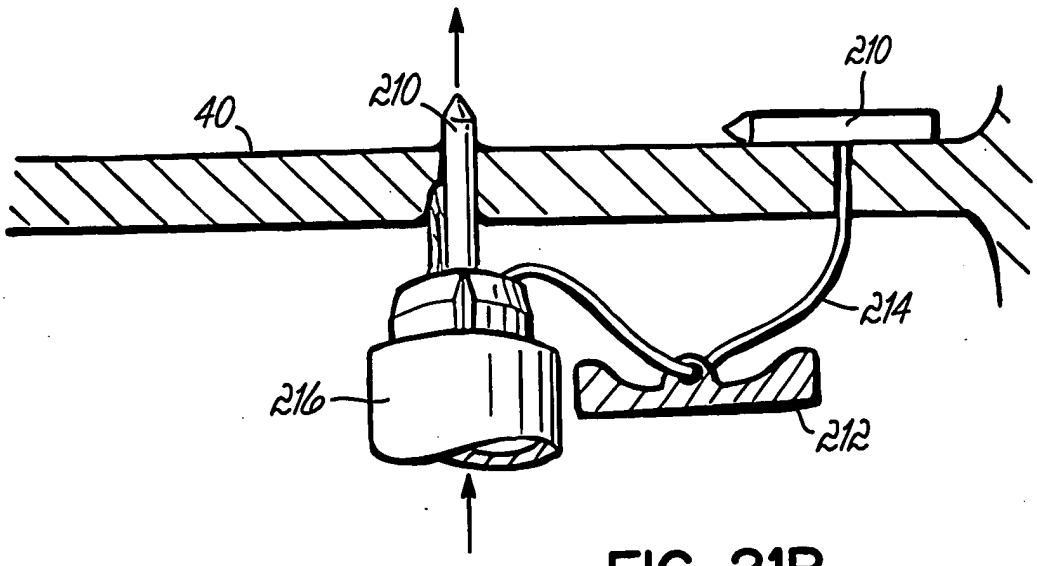


FIG. 21B

FIG. 20A

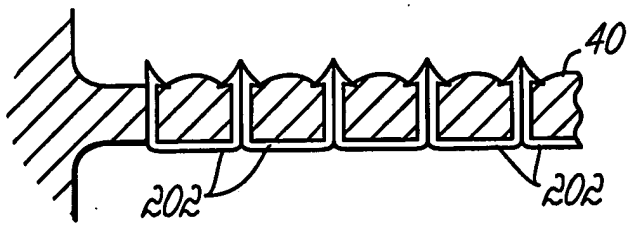


FIG. 20B

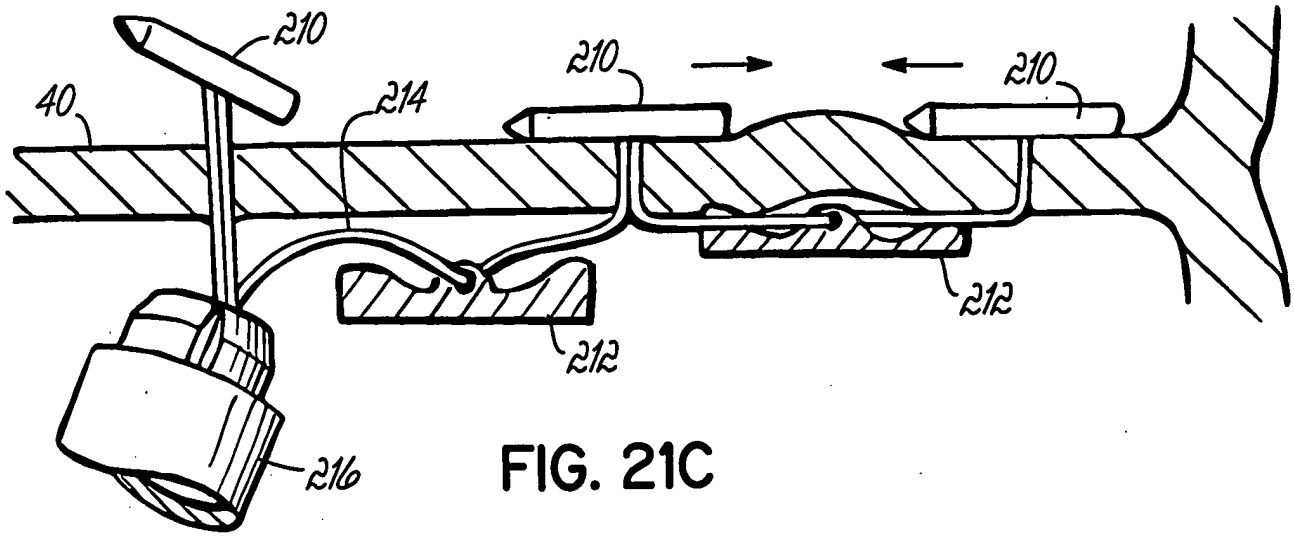


FIG. 21C

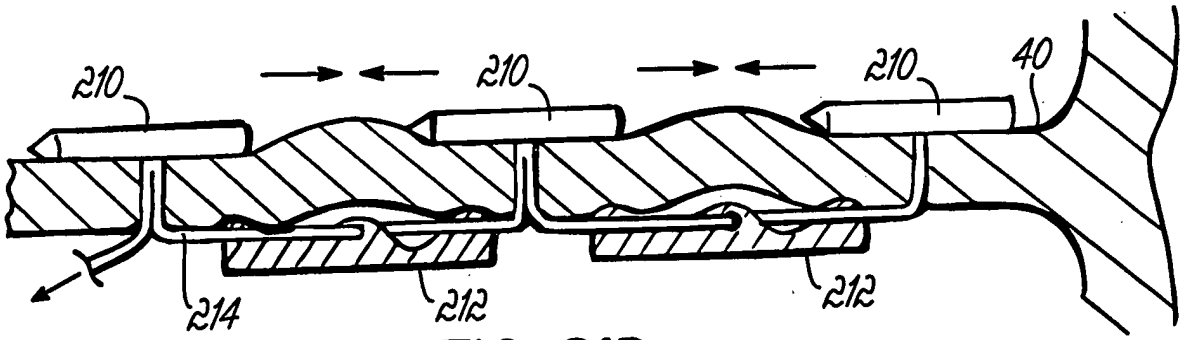


FIG. 21D

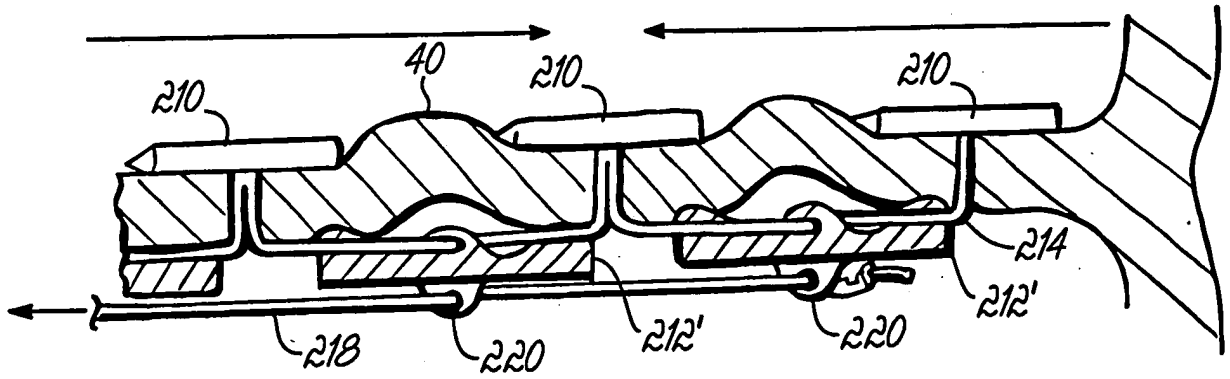


FIG. 22

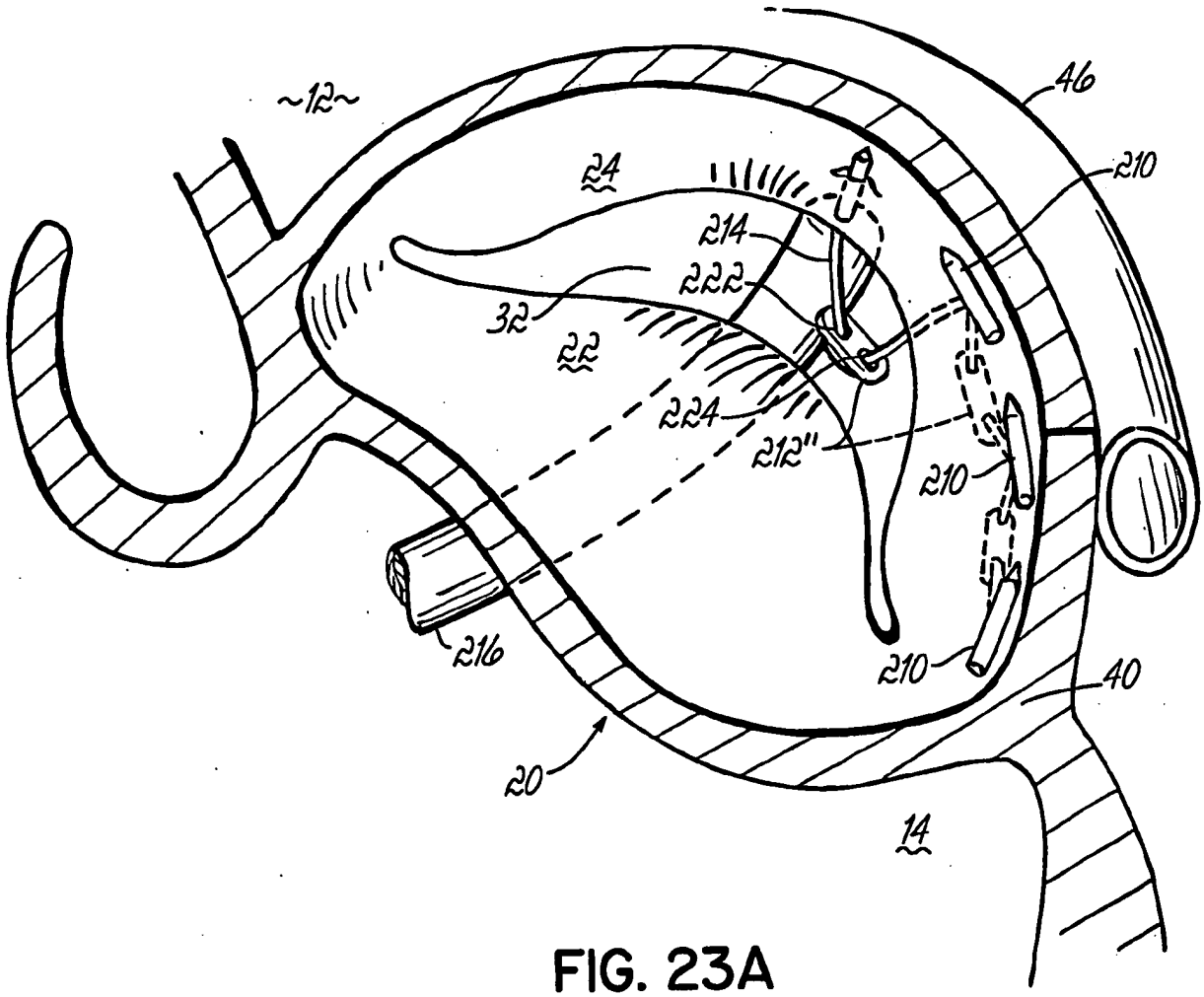


FIG. 23A

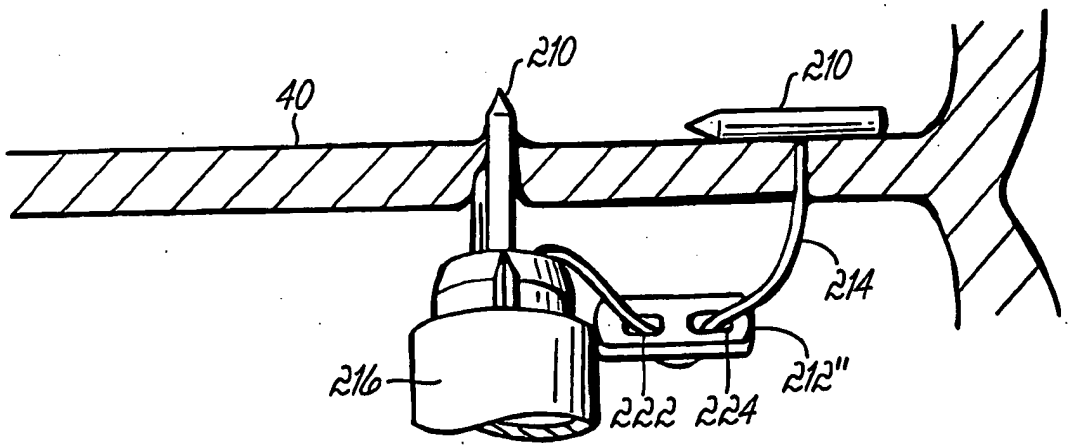


FIG. 23B

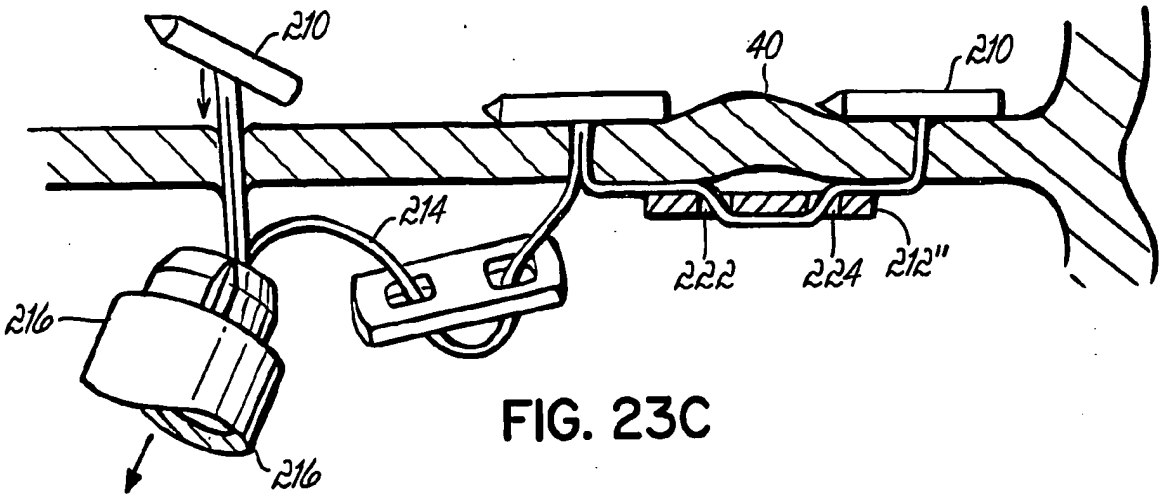


FIG. 23C

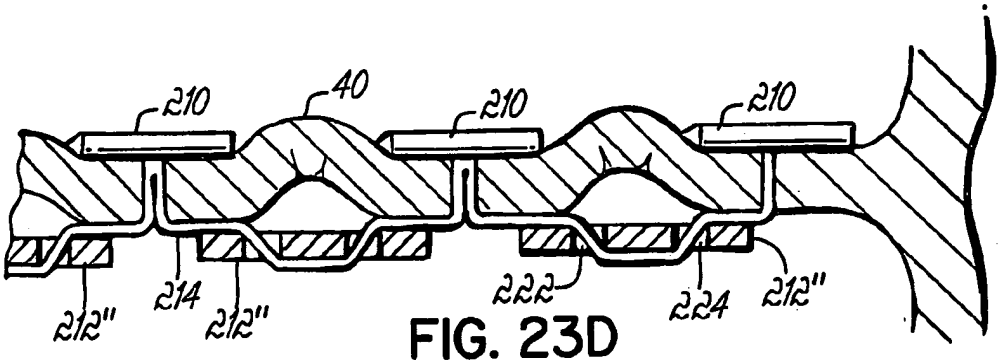


FIG. 23D

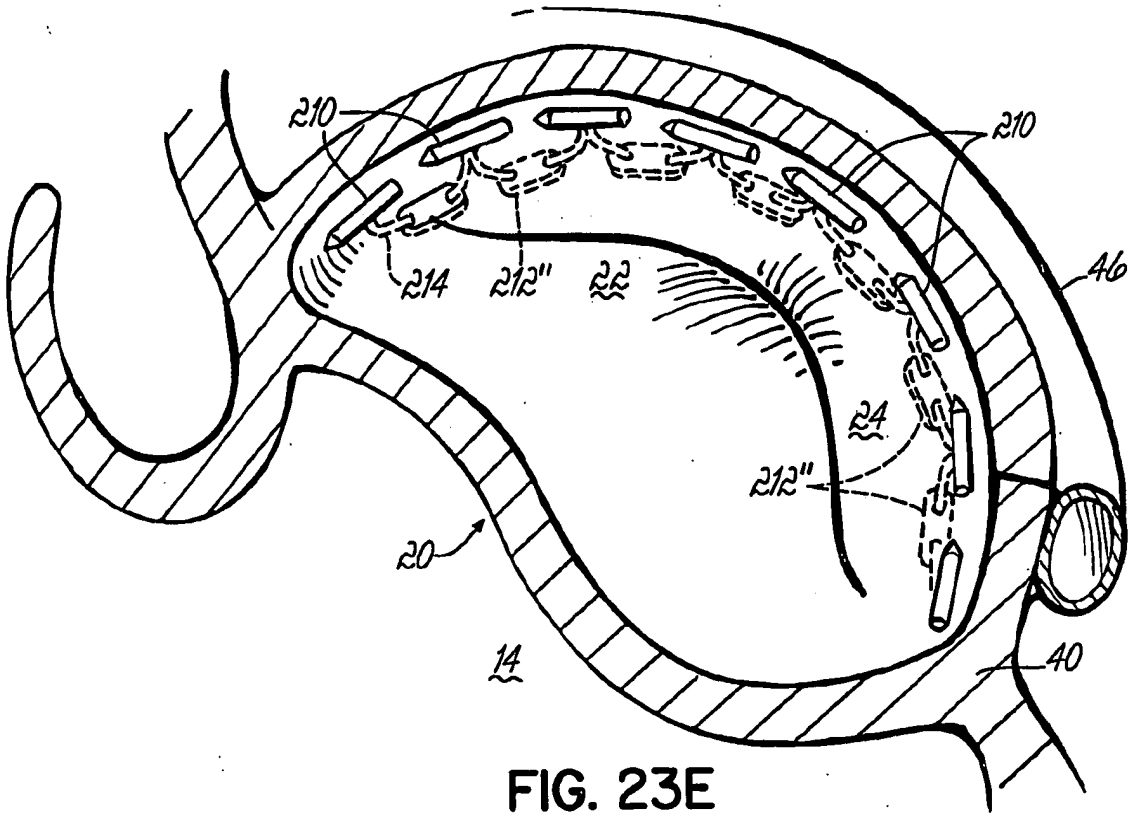


FIG. 23E

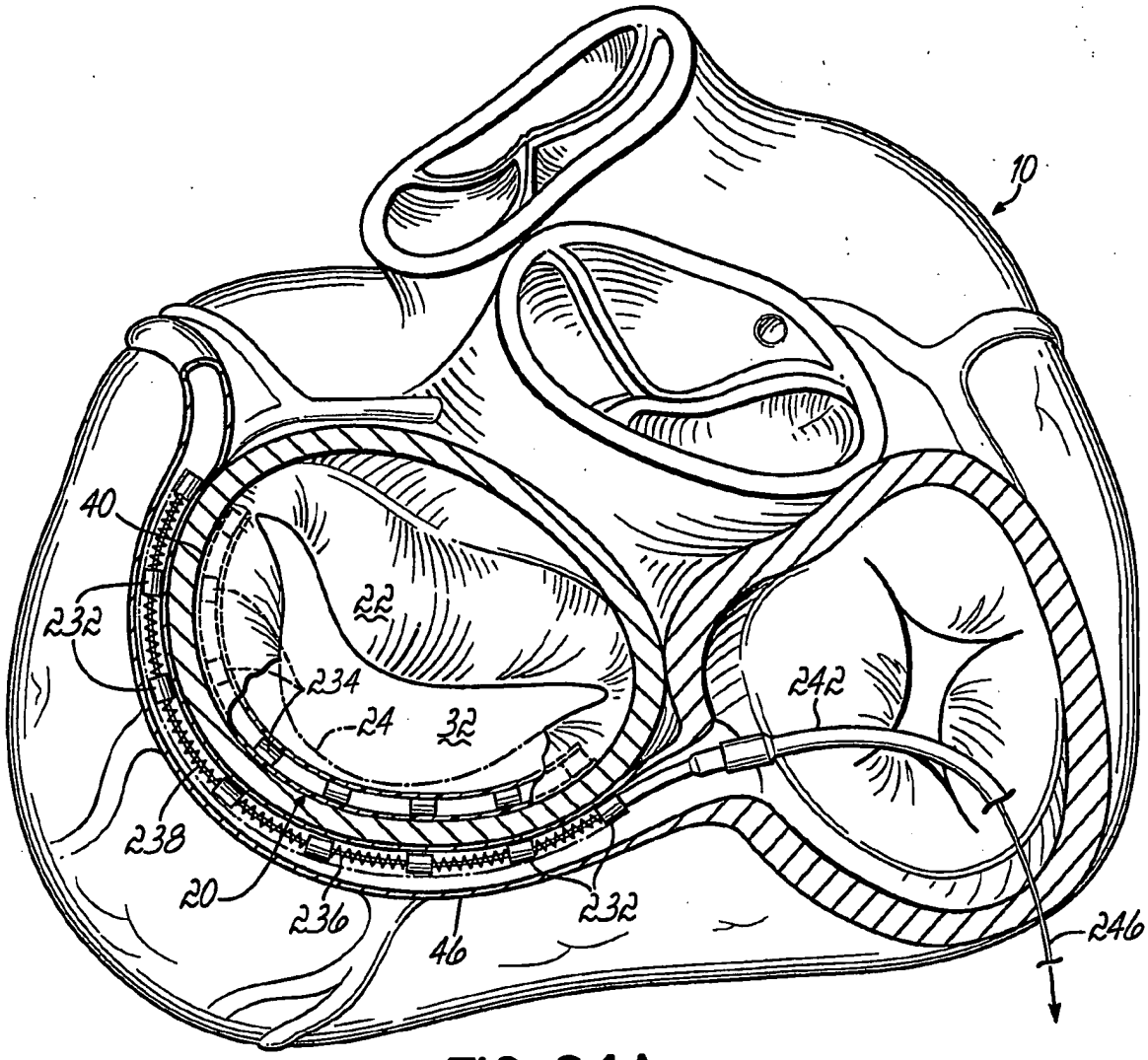


FIG. 24A

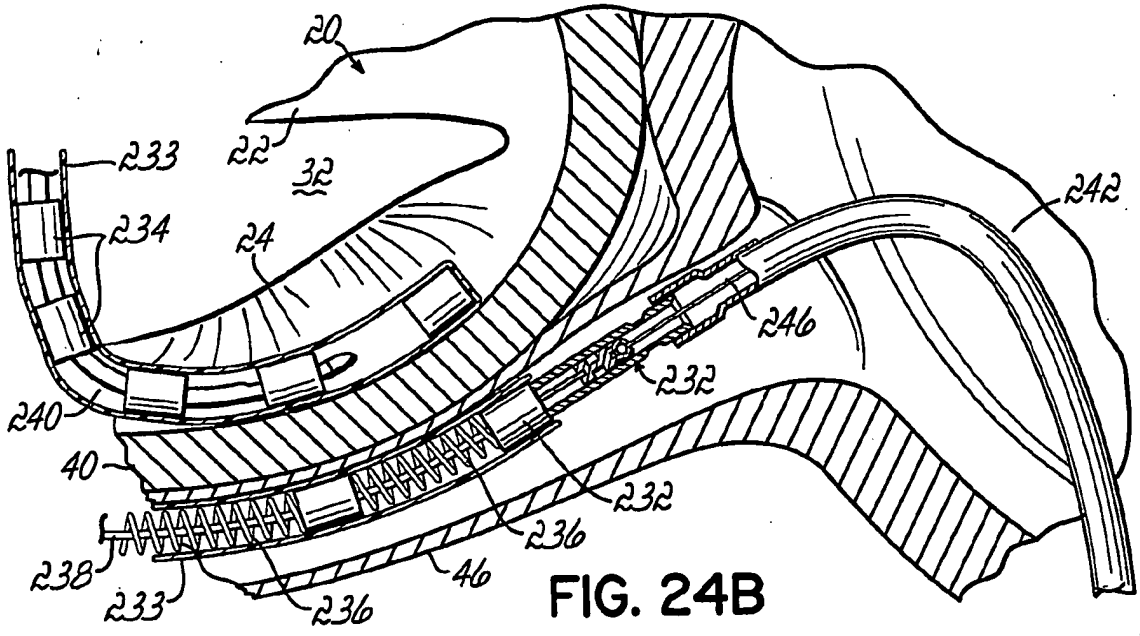


FIG. 24B

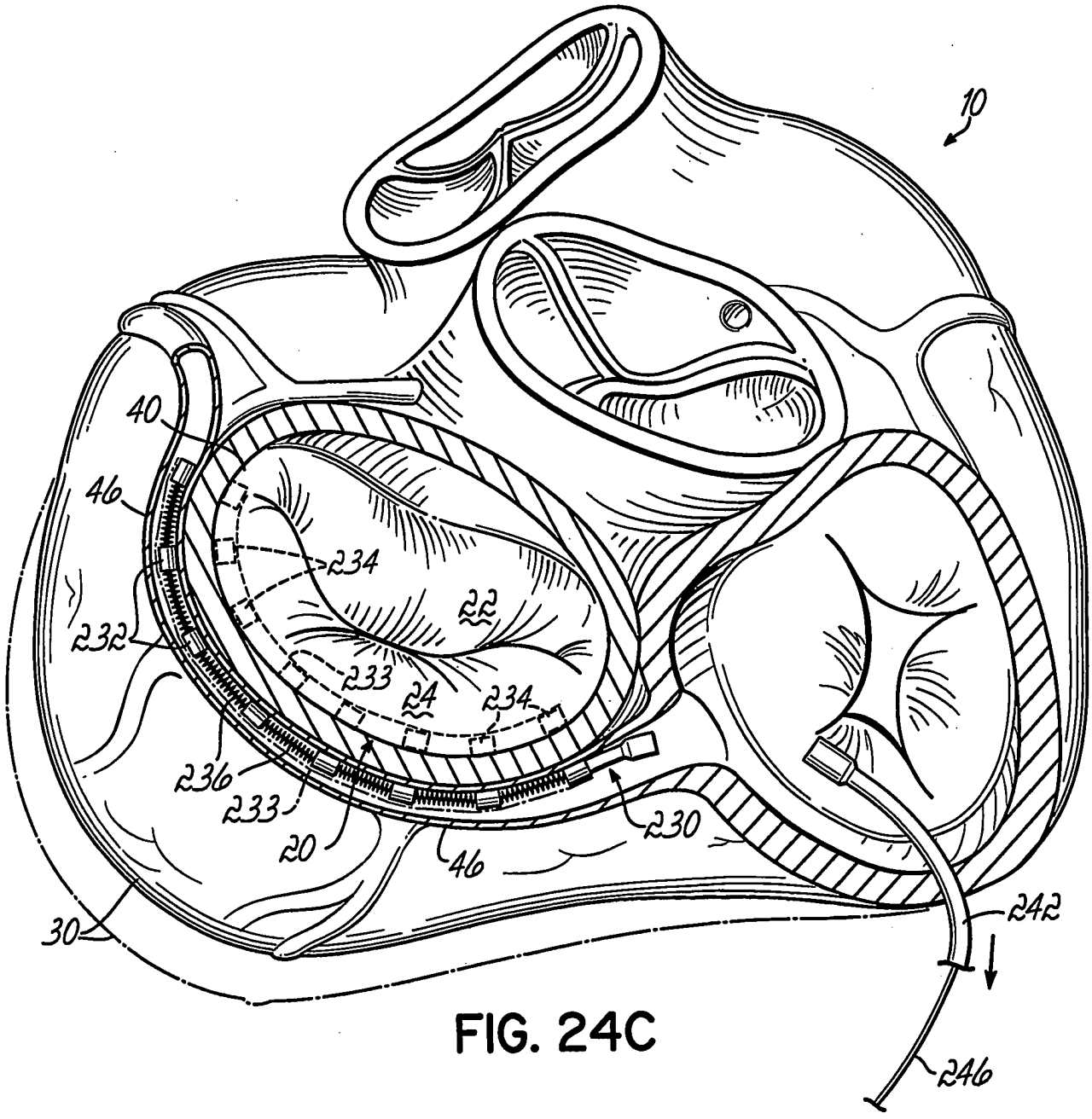


FIG. 24C

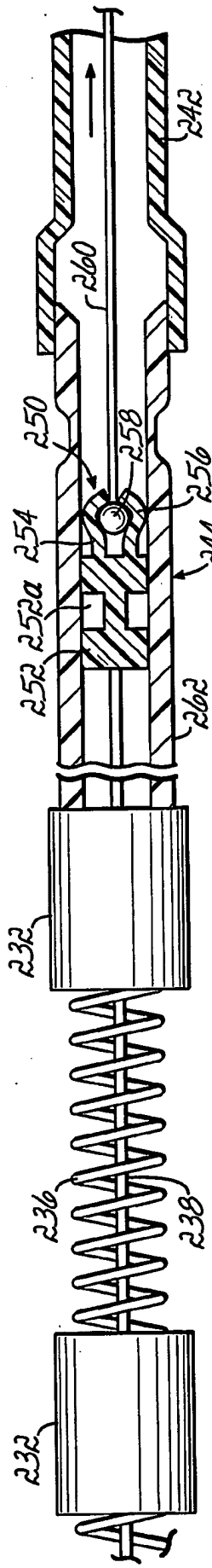


FIG. 25A

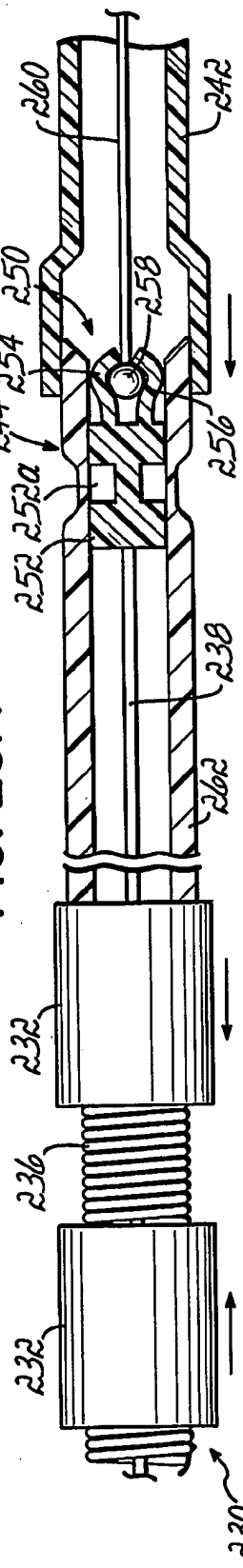


FIG. 25B

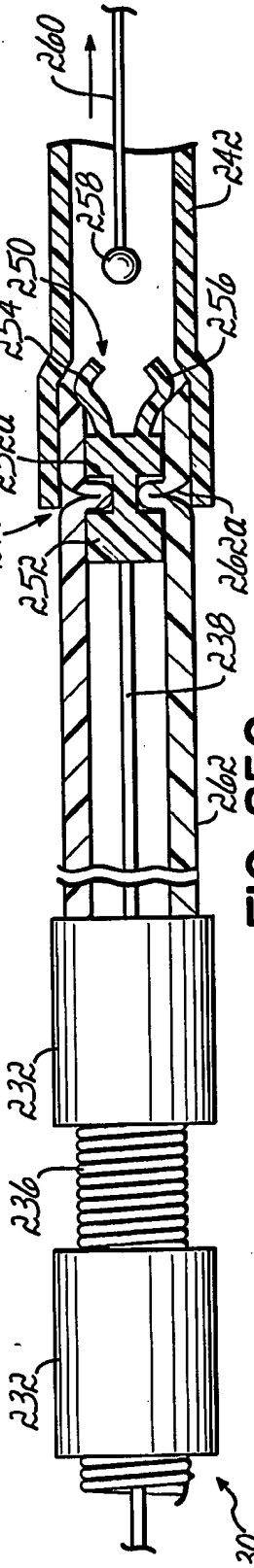


FIG. 25C

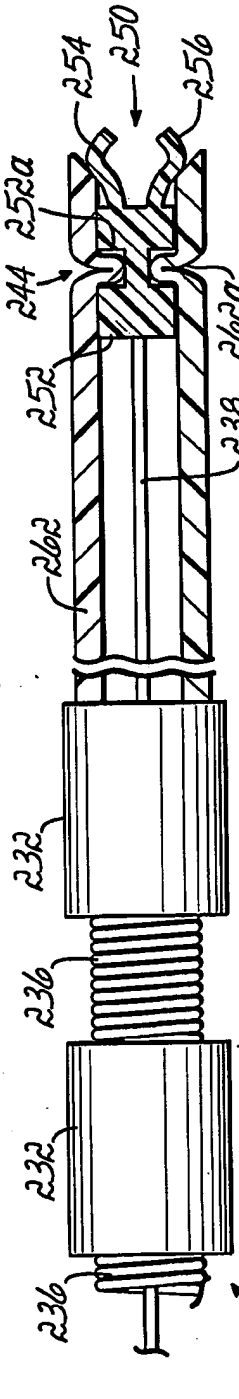


FIG. 25D

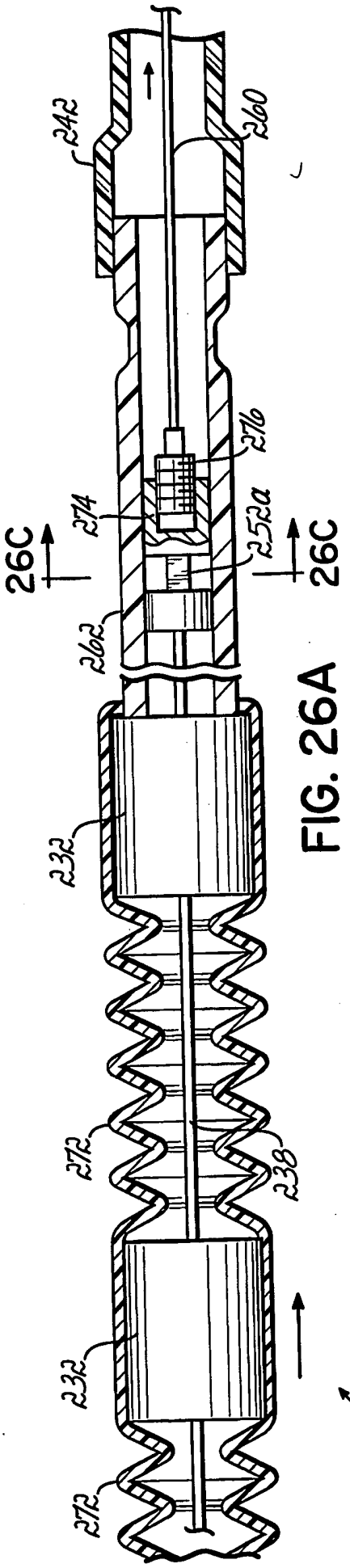


FIG. 26A

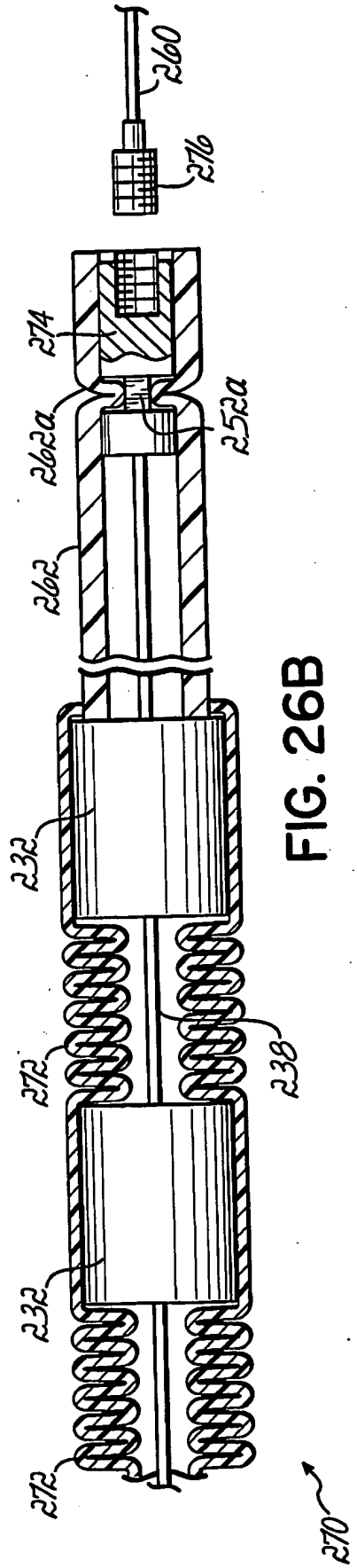


FIG. 26B

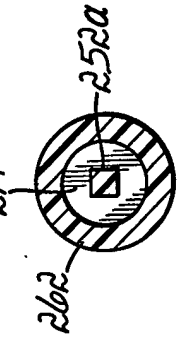


FIG. 26C

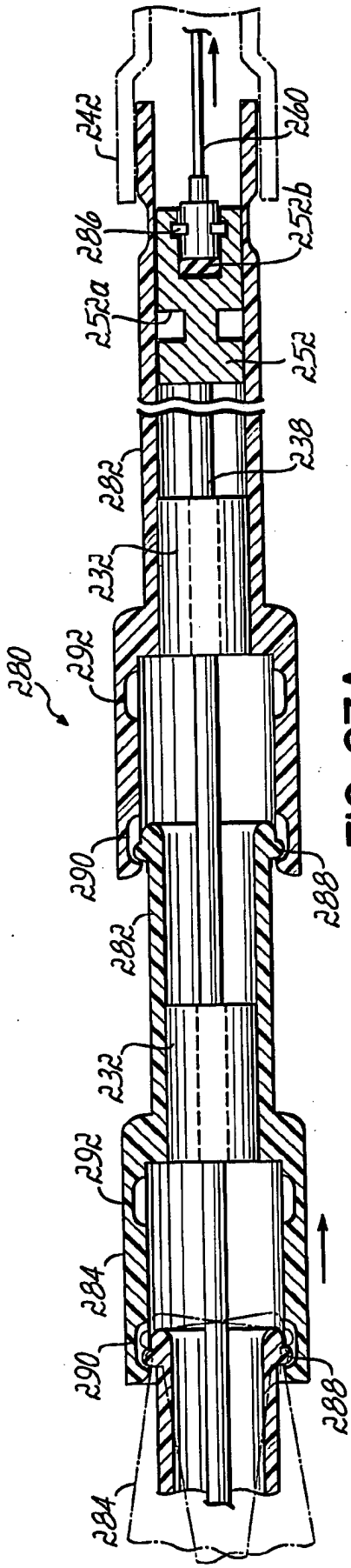


FIG. 27A

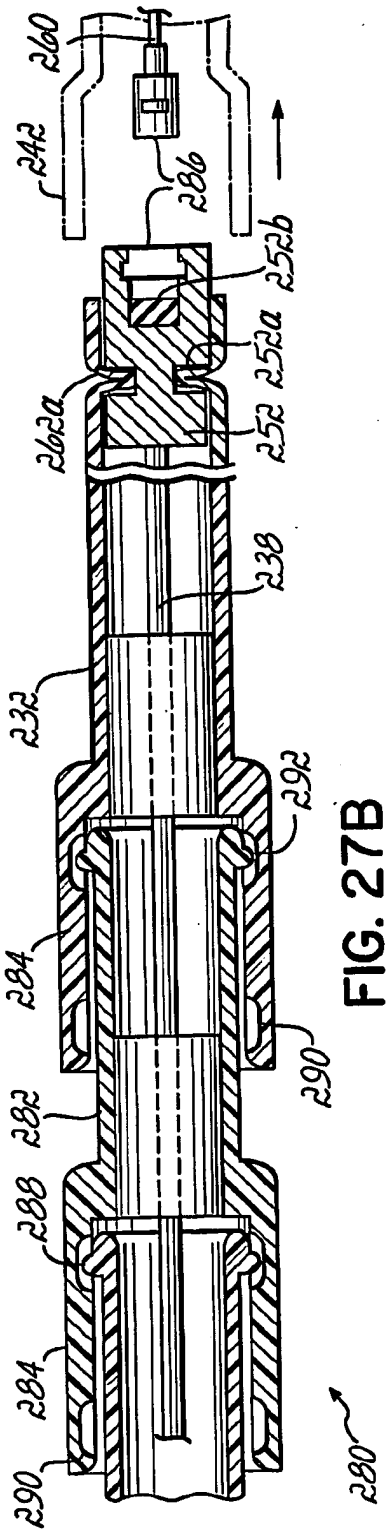


FIG. 27B

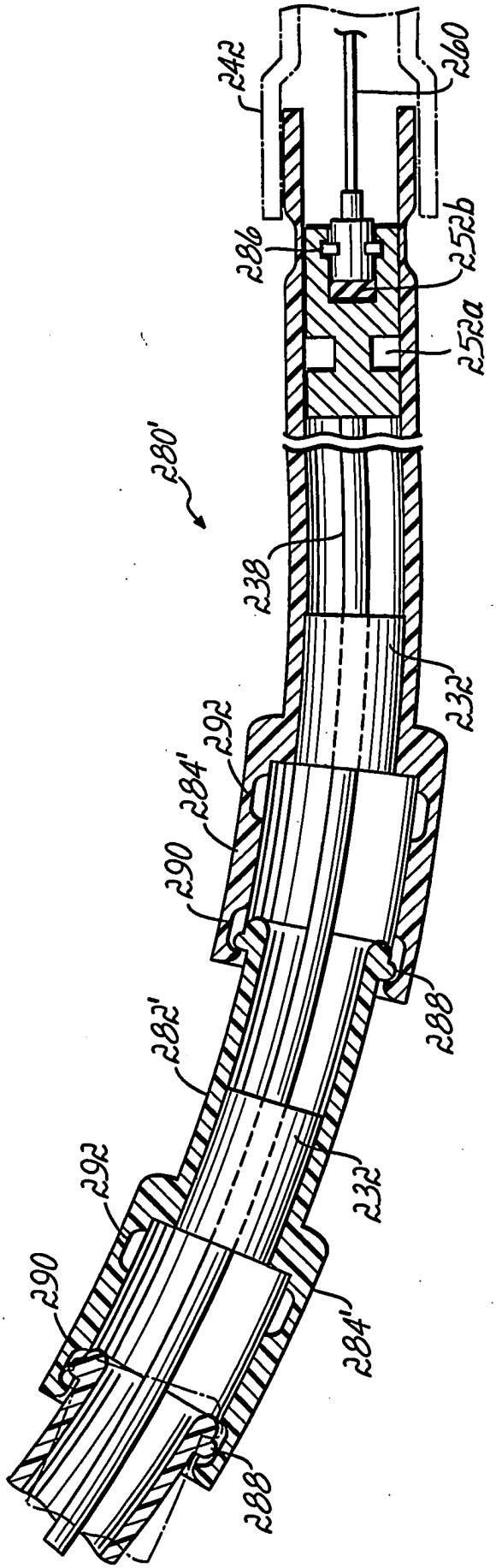


FIG. 28A

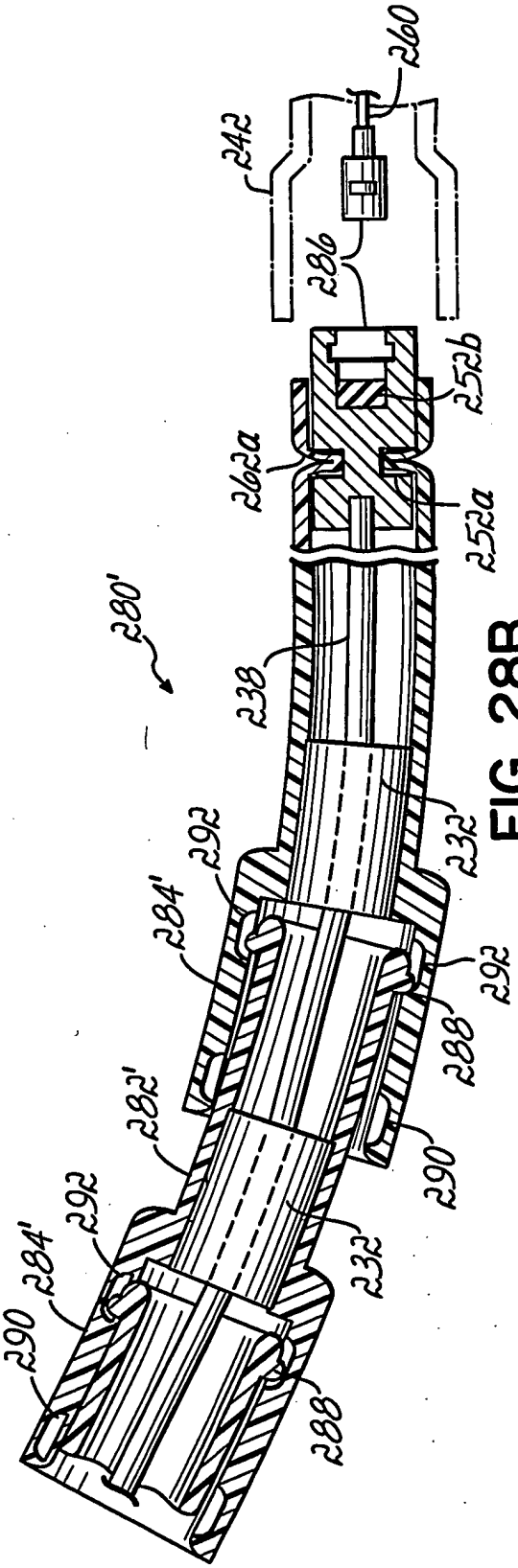


FIG. 28B

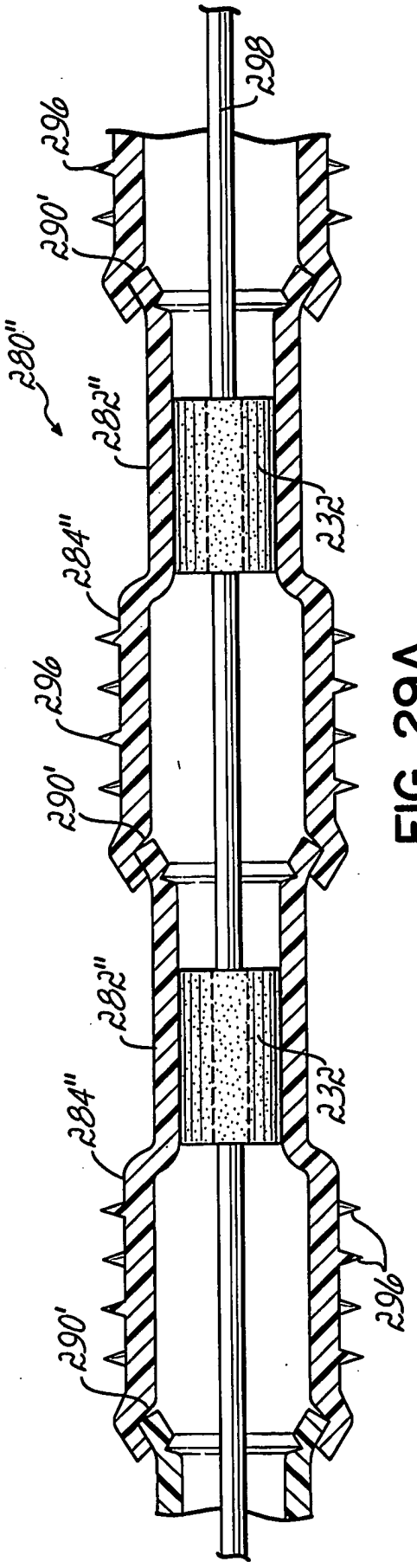


FIG. 29A

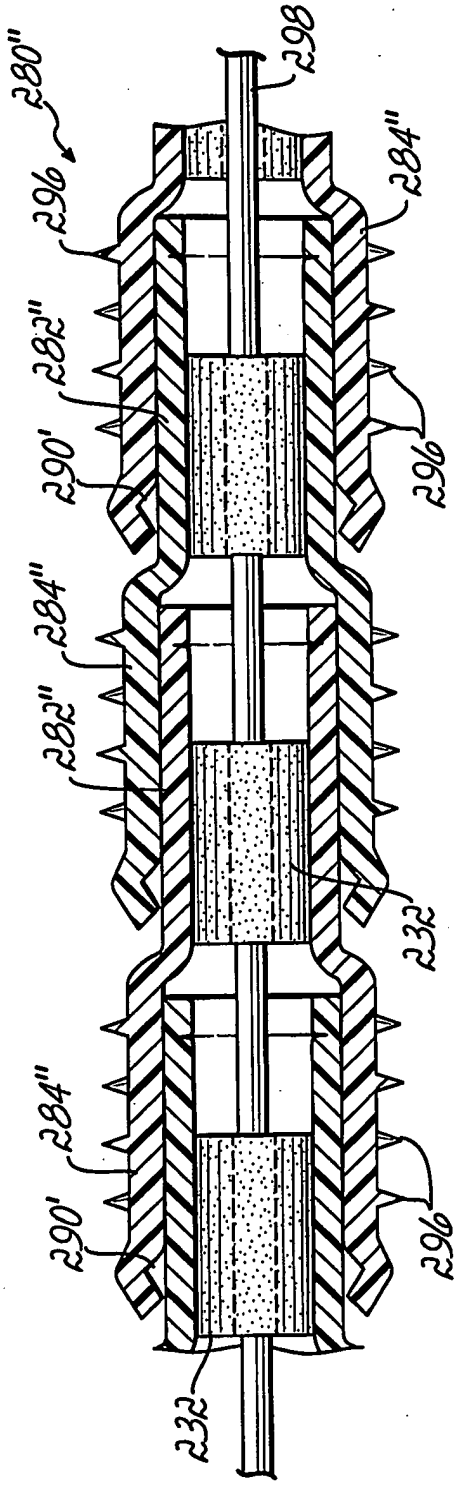


FIG. 29B

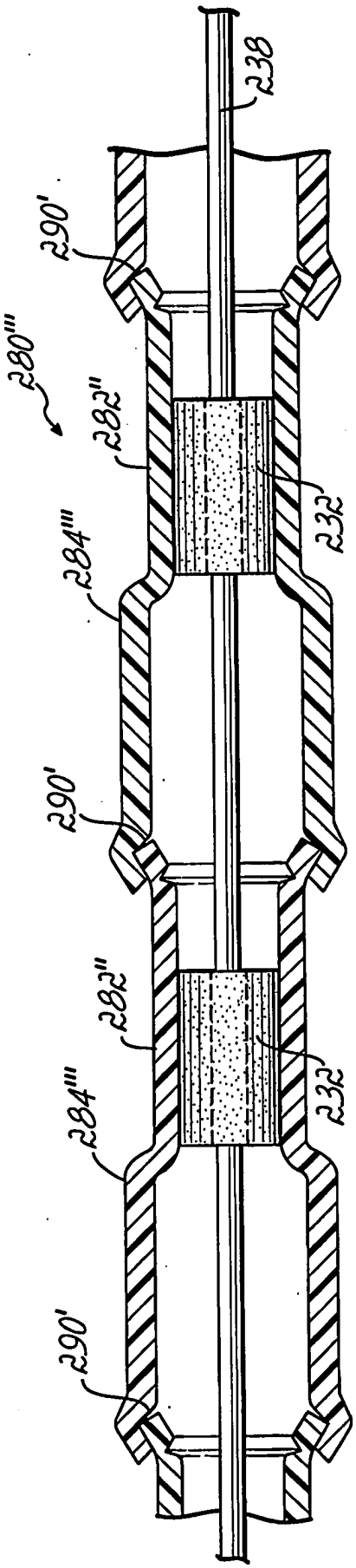


FIG. 29C

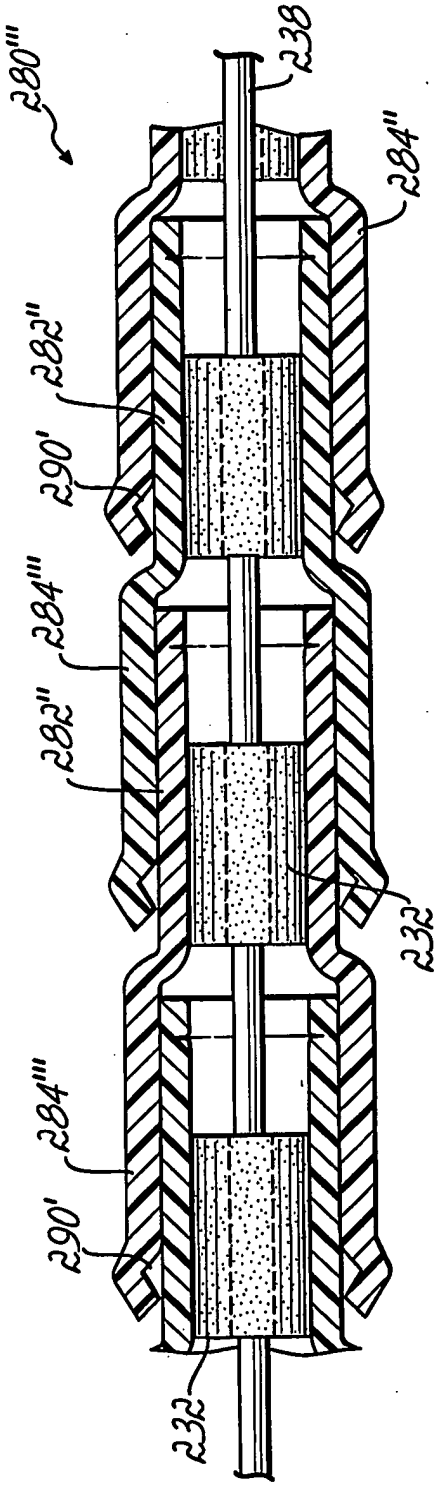


FIG. 29D

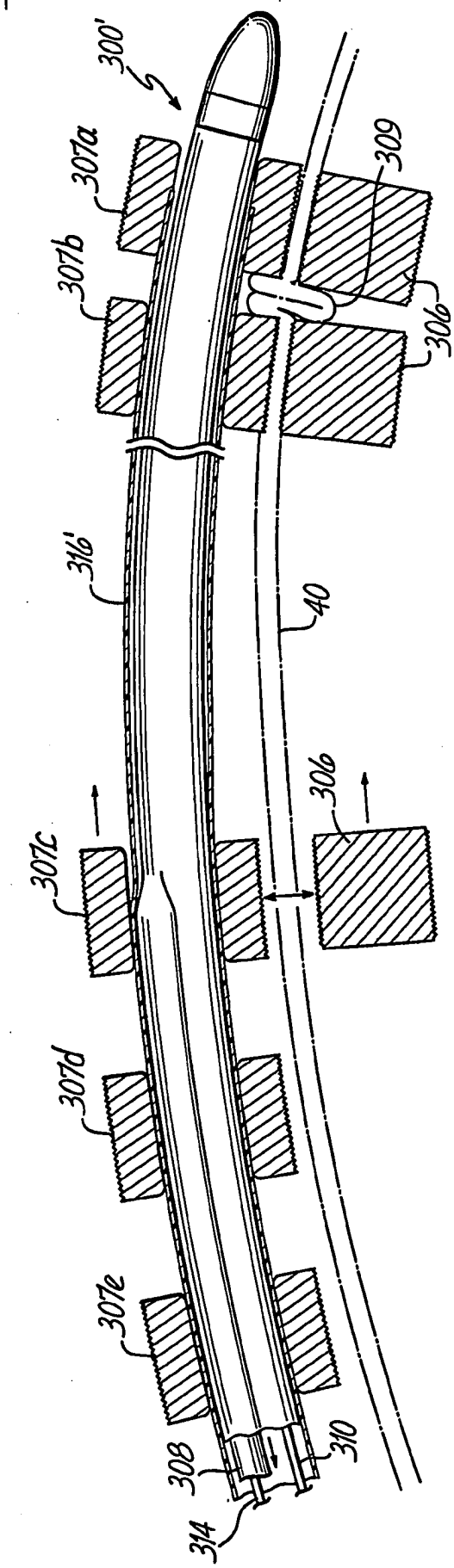


FIG. 30B

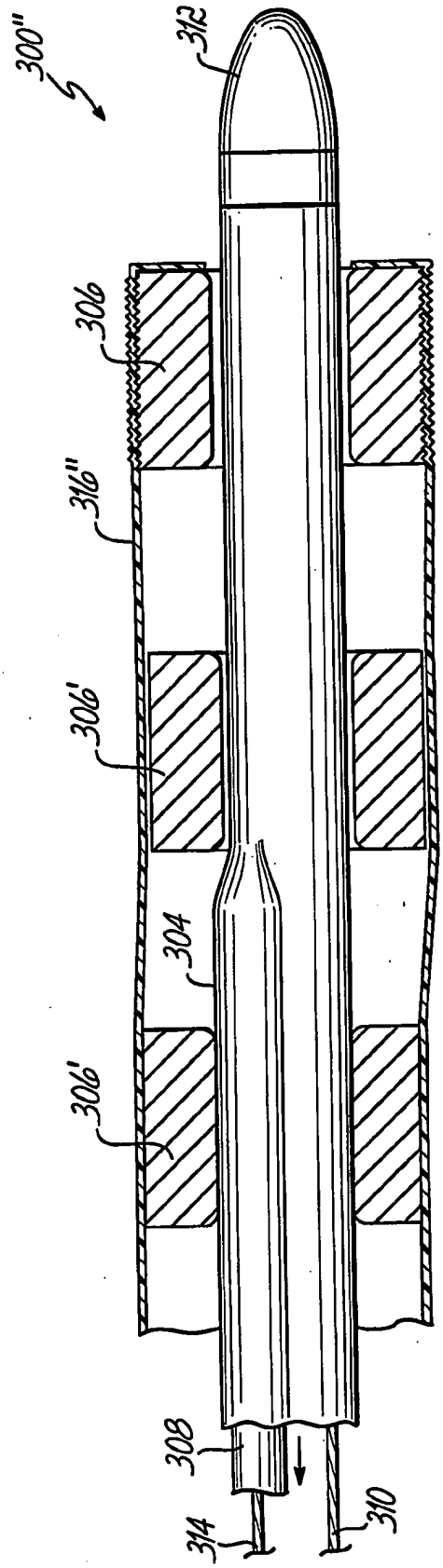


FIG. 30C

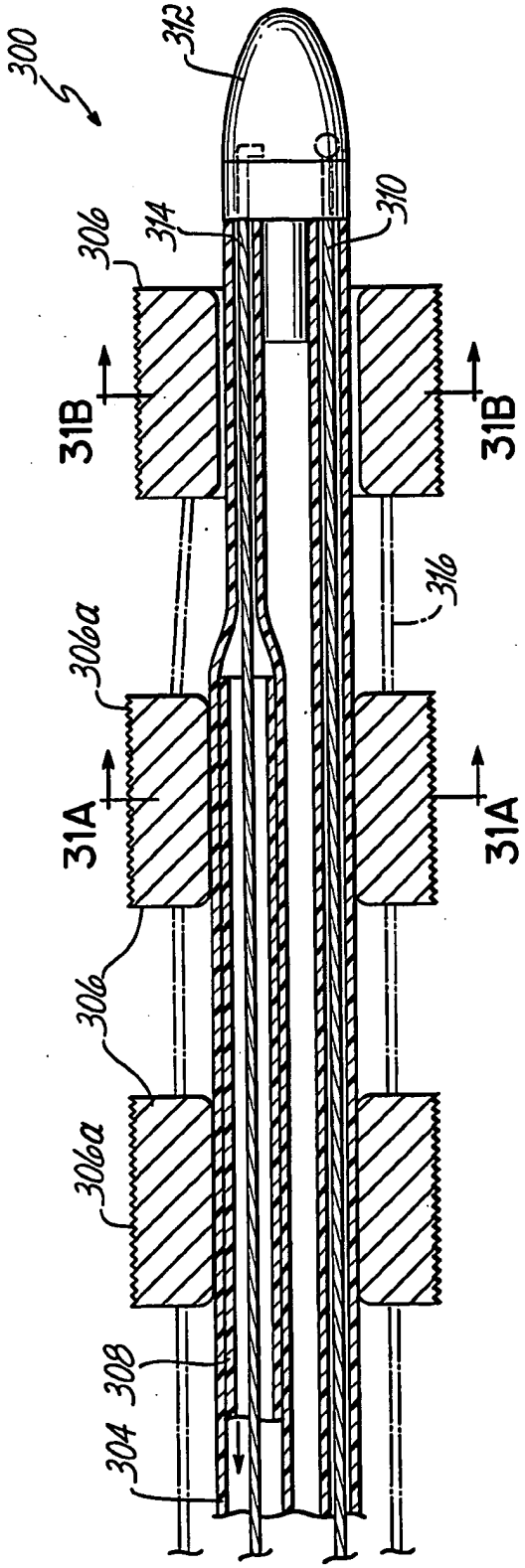


FIG. 30

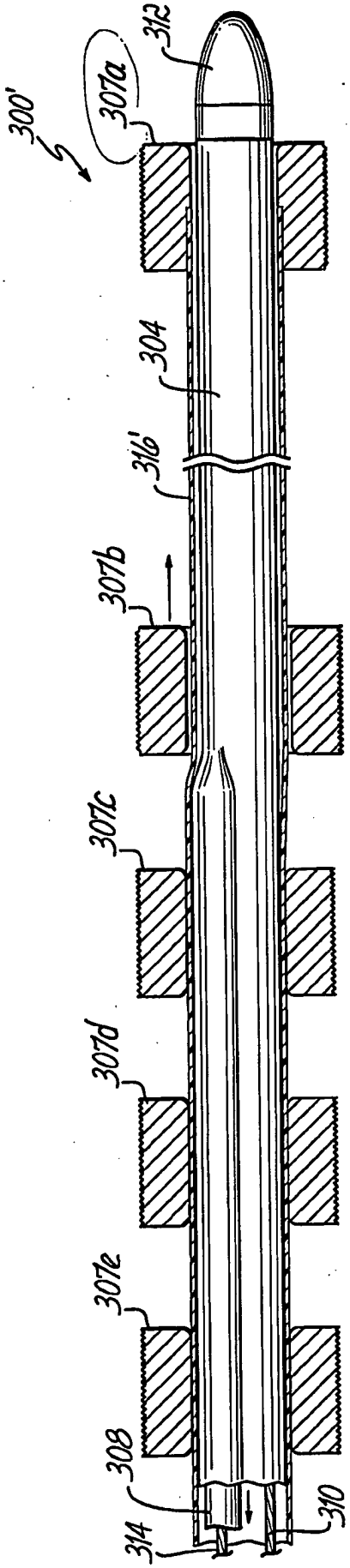


FIG. 30A

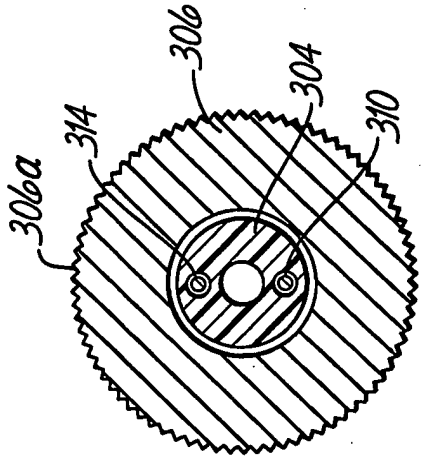


FIG. 31B

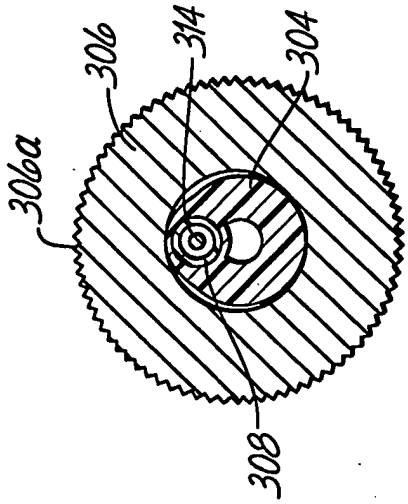


FIG. 31A

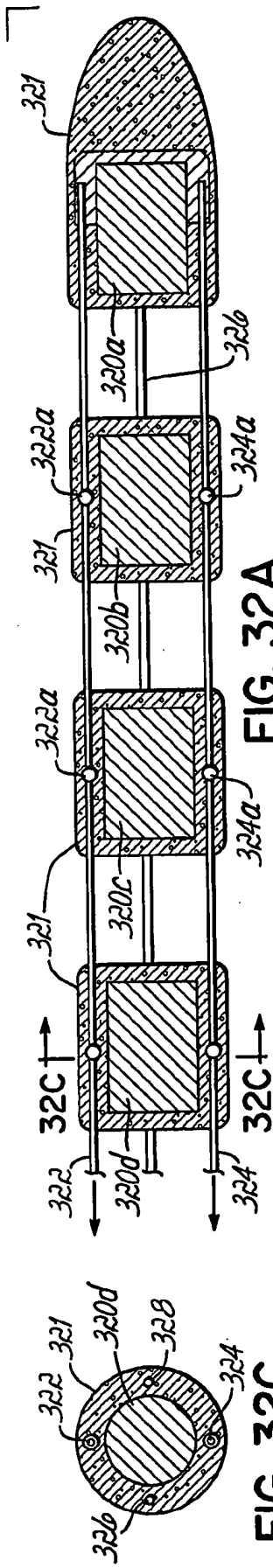


FIG. 32A

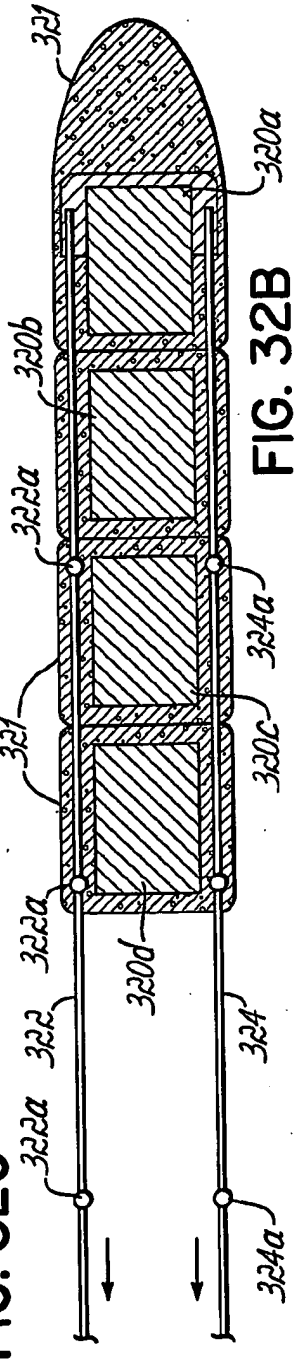


FIG. 32B

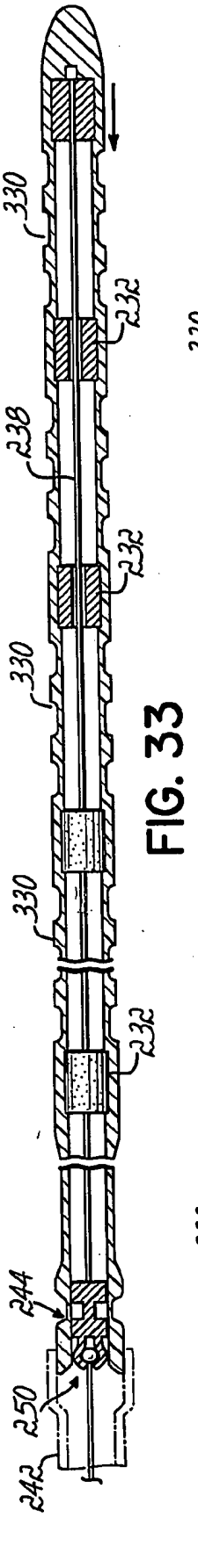


FIG. 33

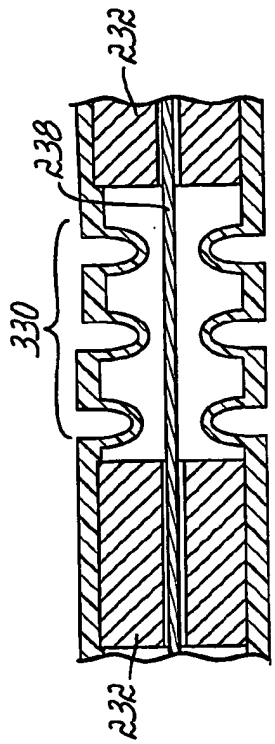


FIG. 33B

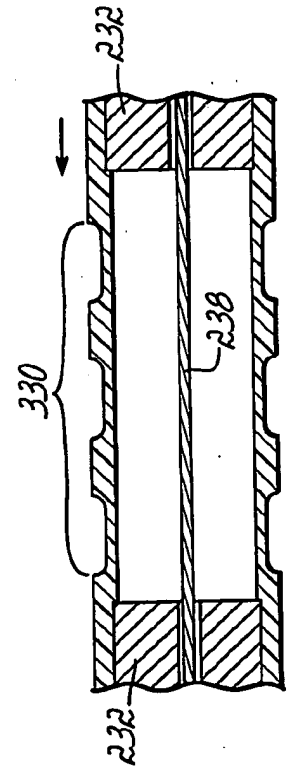


FIG. 33A

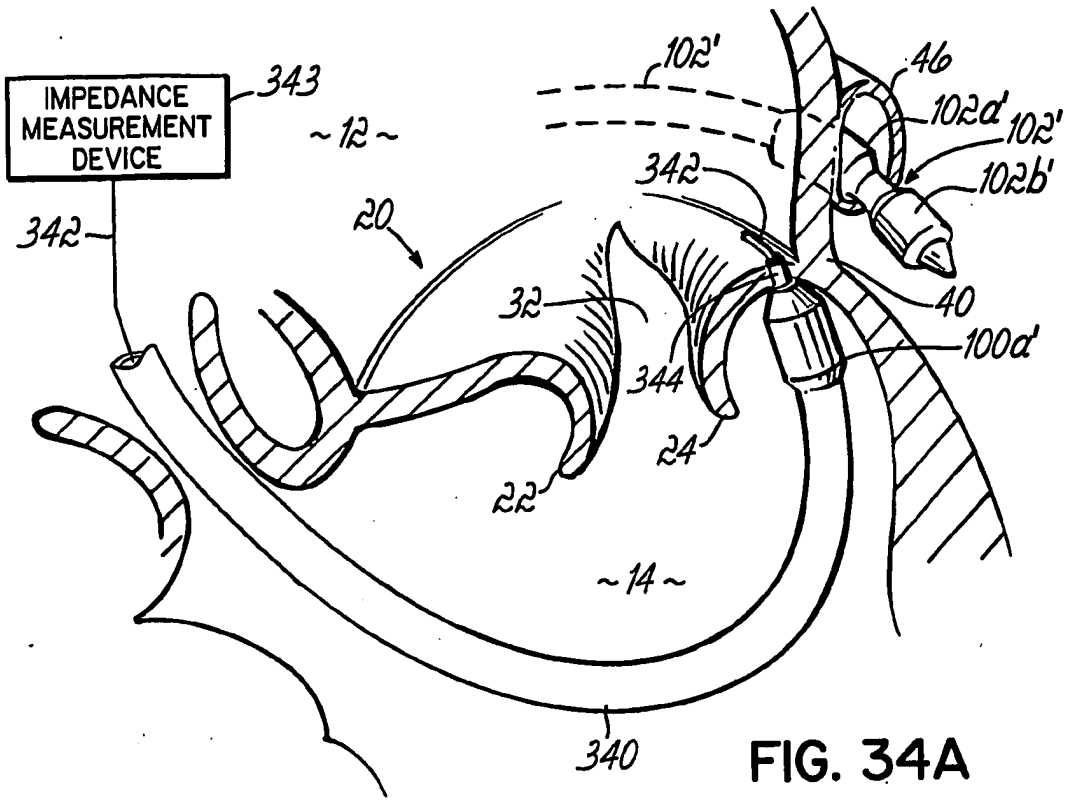


FIG. 34A

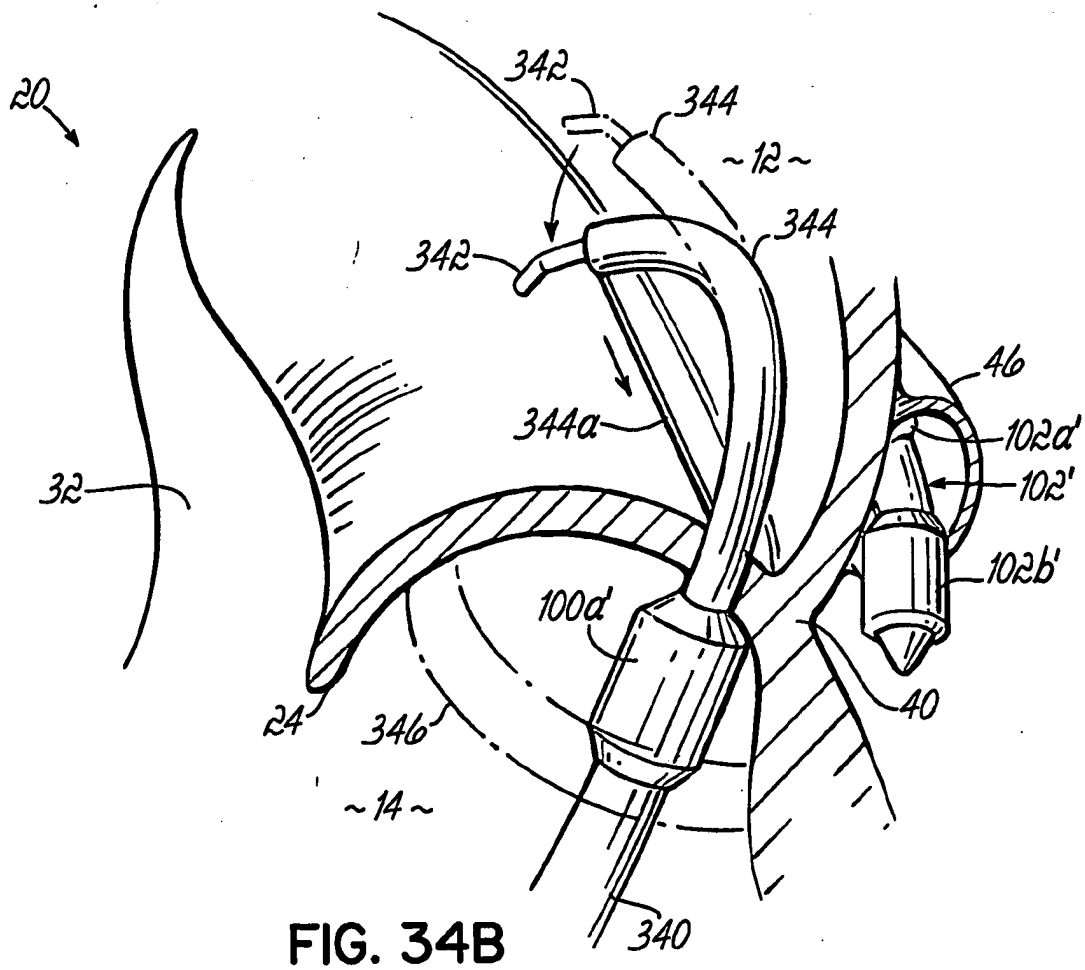


FIG. 34B

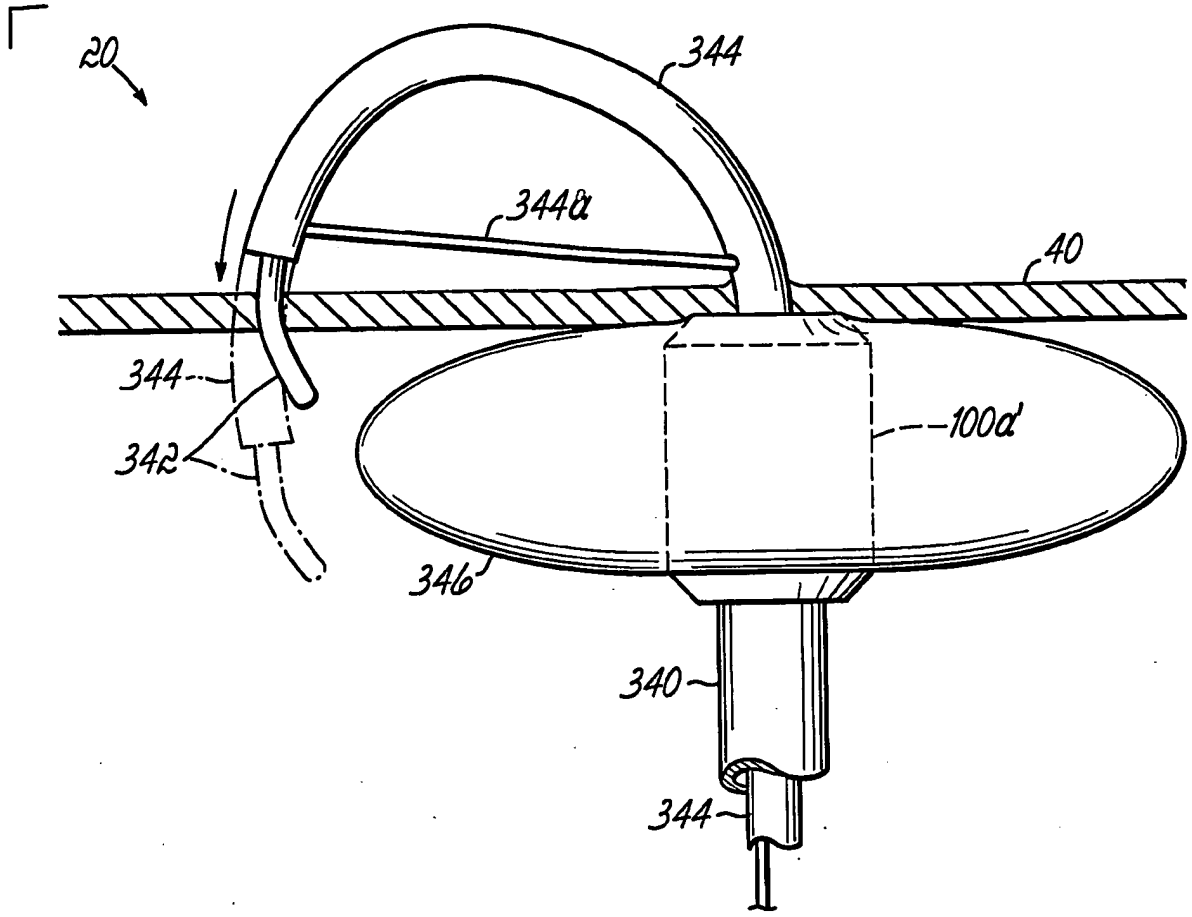


FIG. 34C

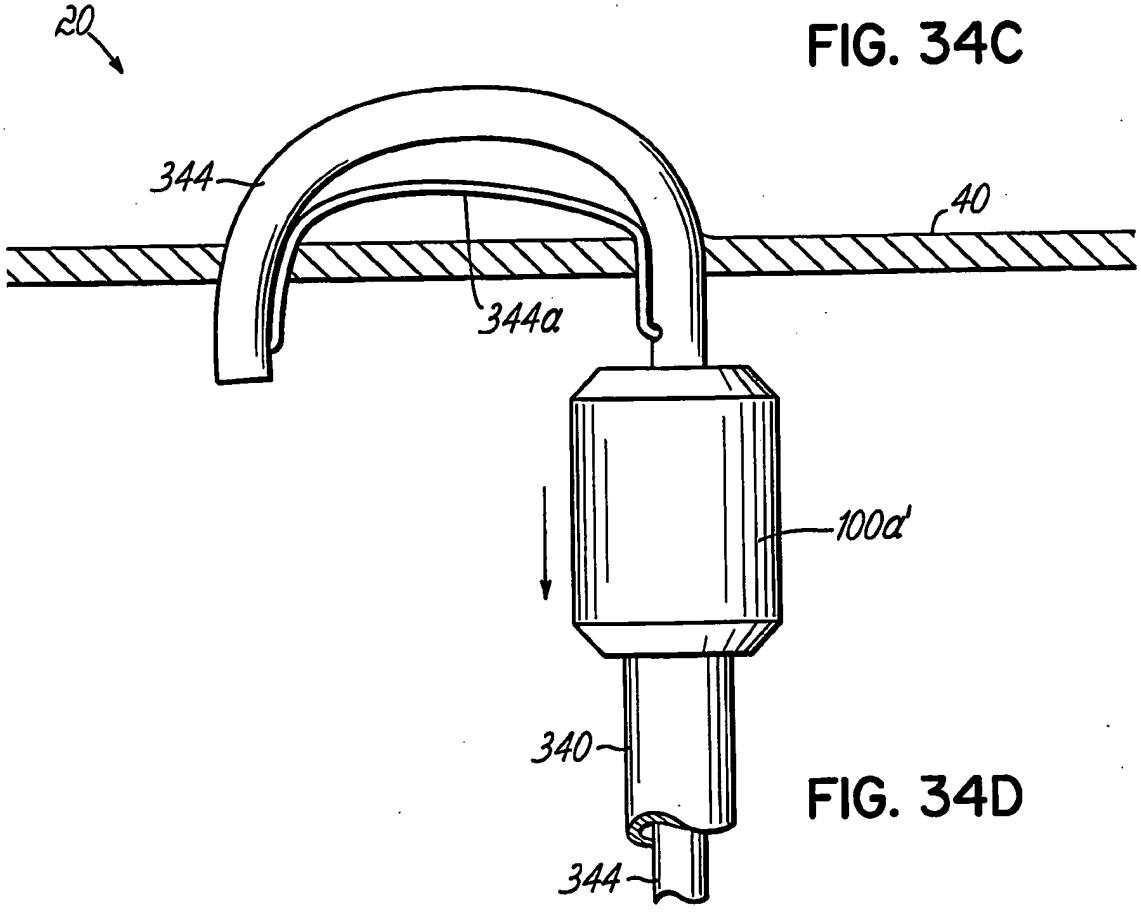


FIG. 34D

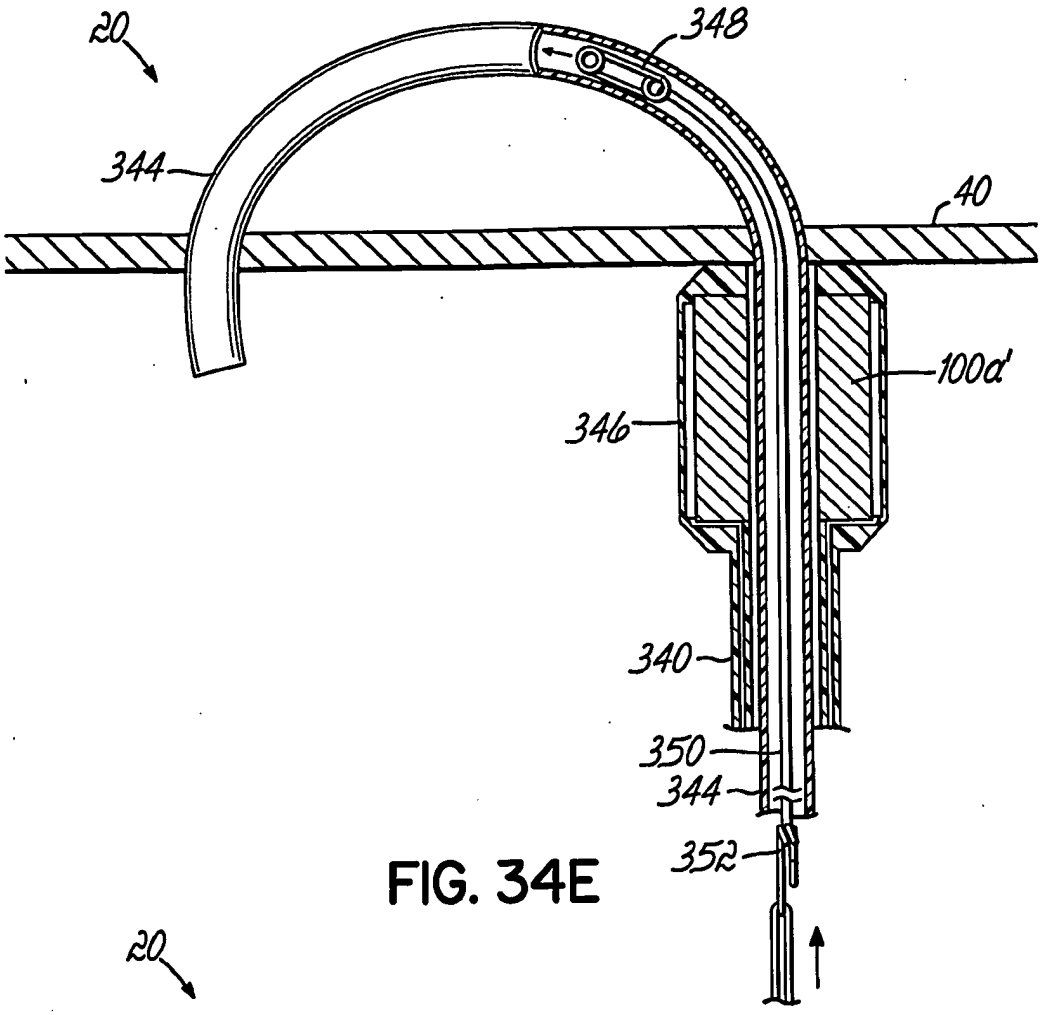


FIG. 34E

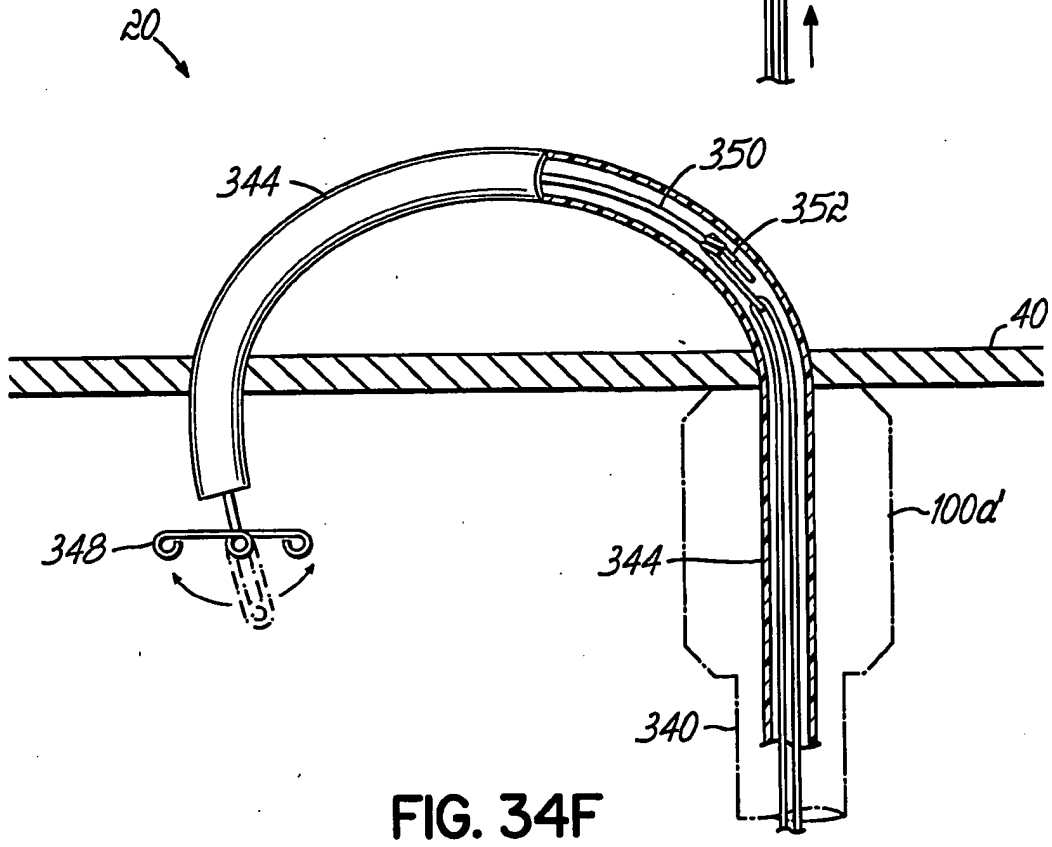


FIG. 34F

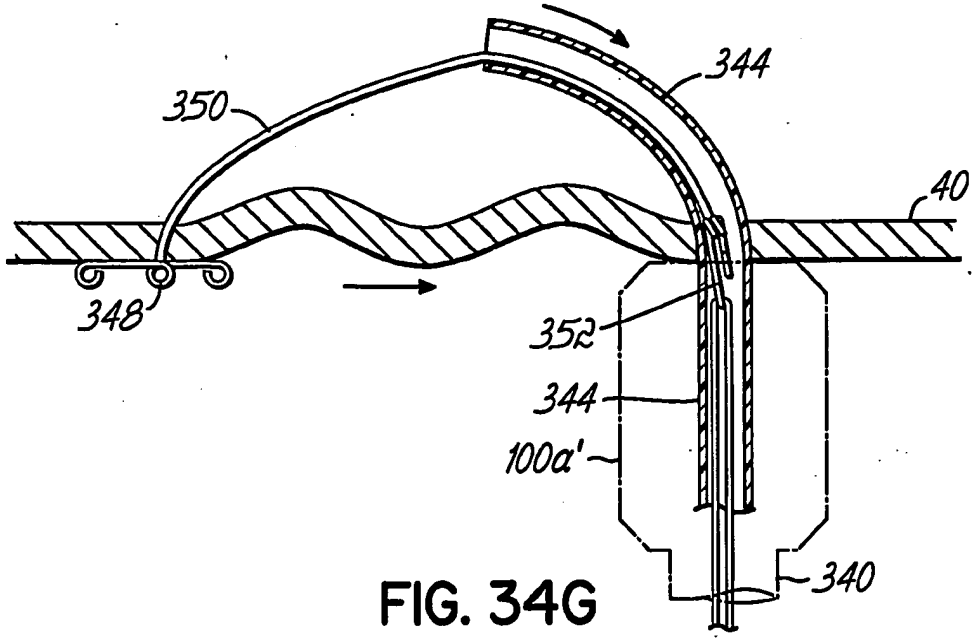


FIG. 34G

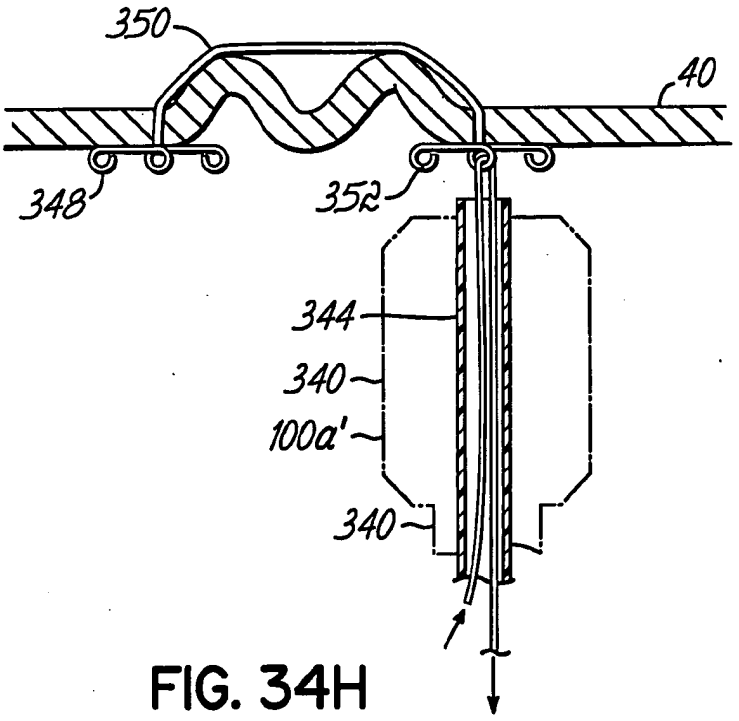


FIG. 34H

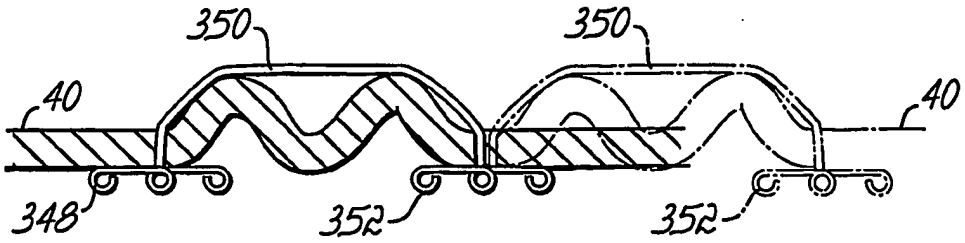


FIG. 34I

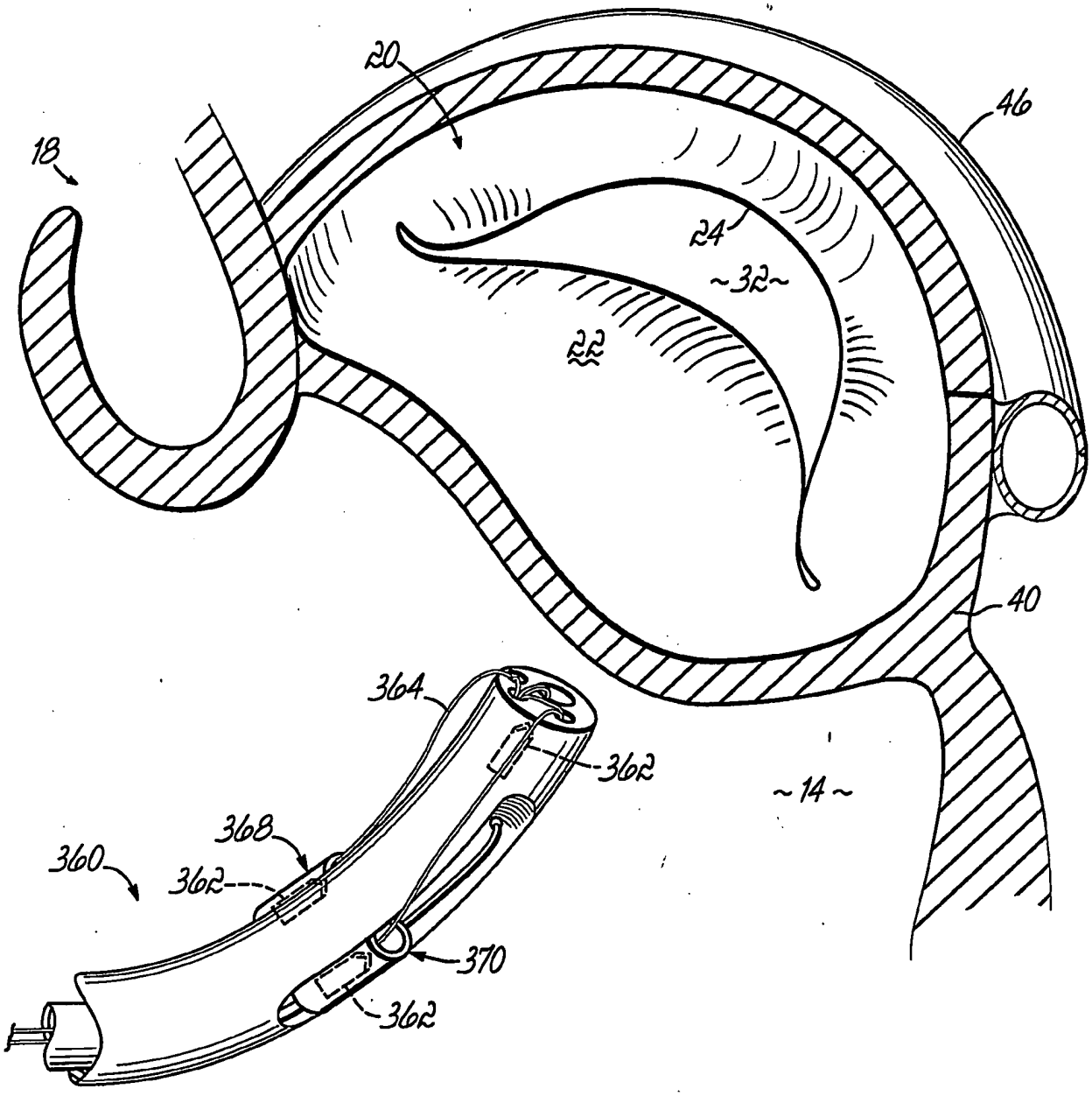


FIG. 35A

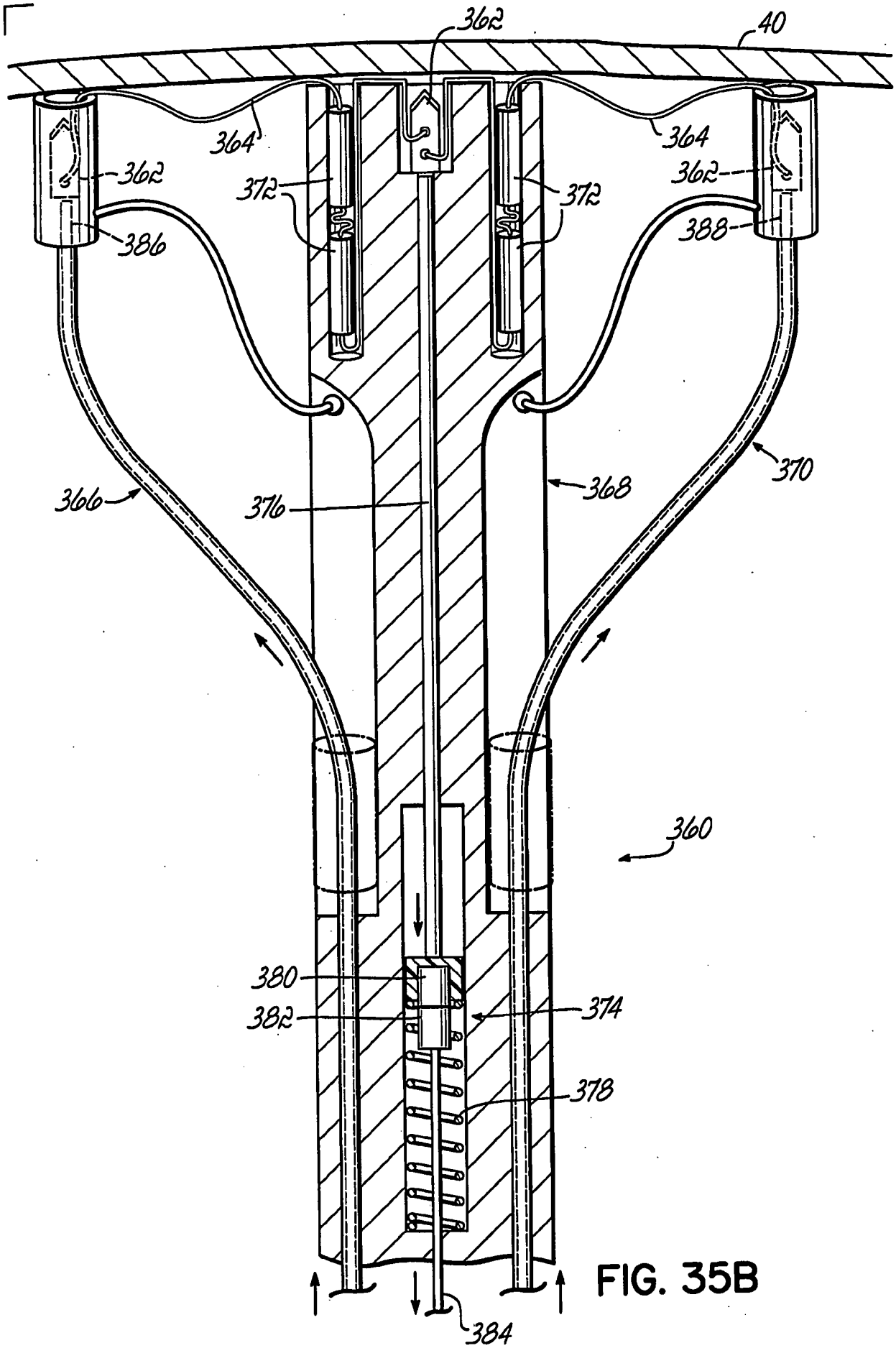

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FIG. 35B

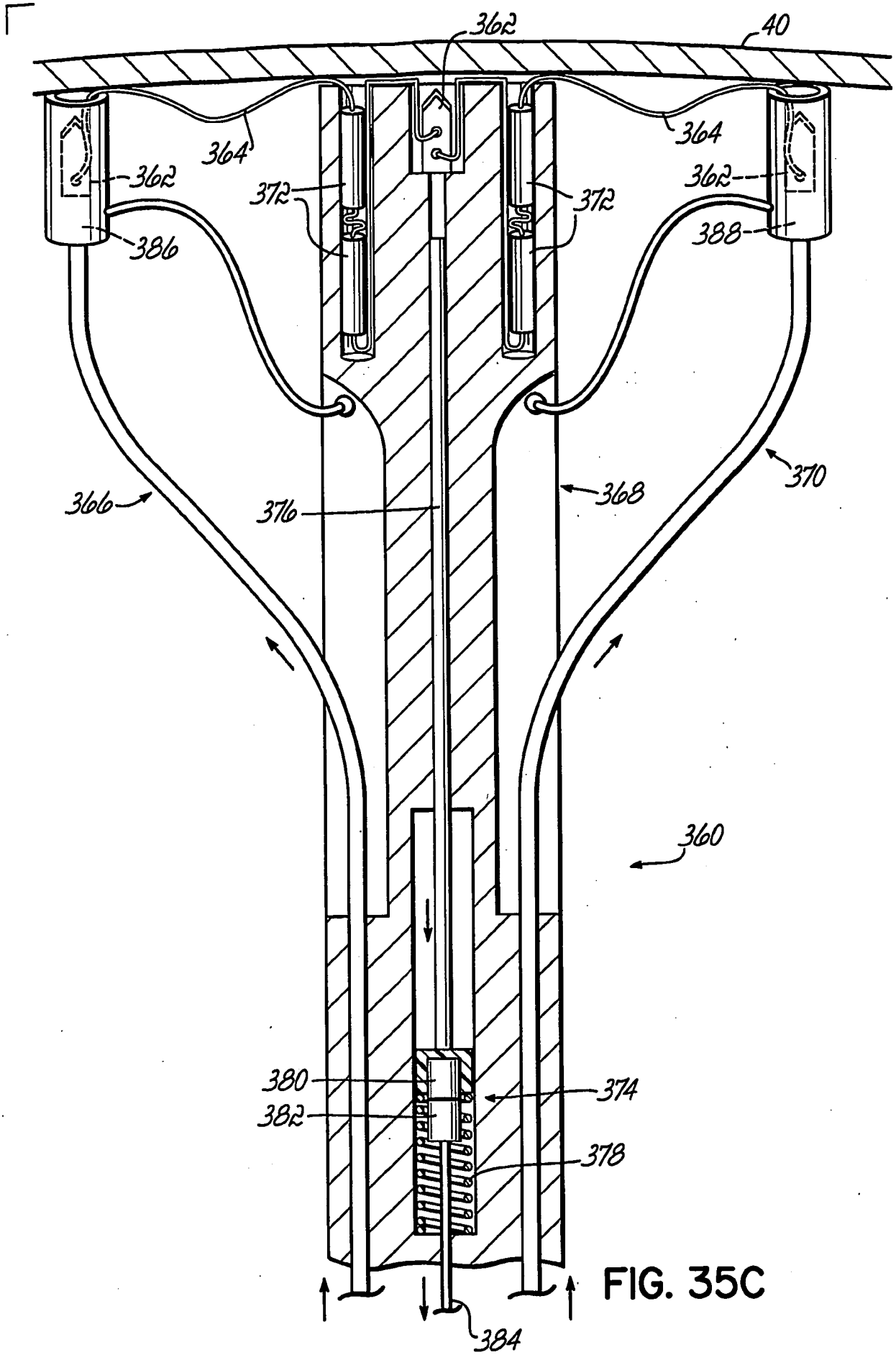
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FIG. 35C

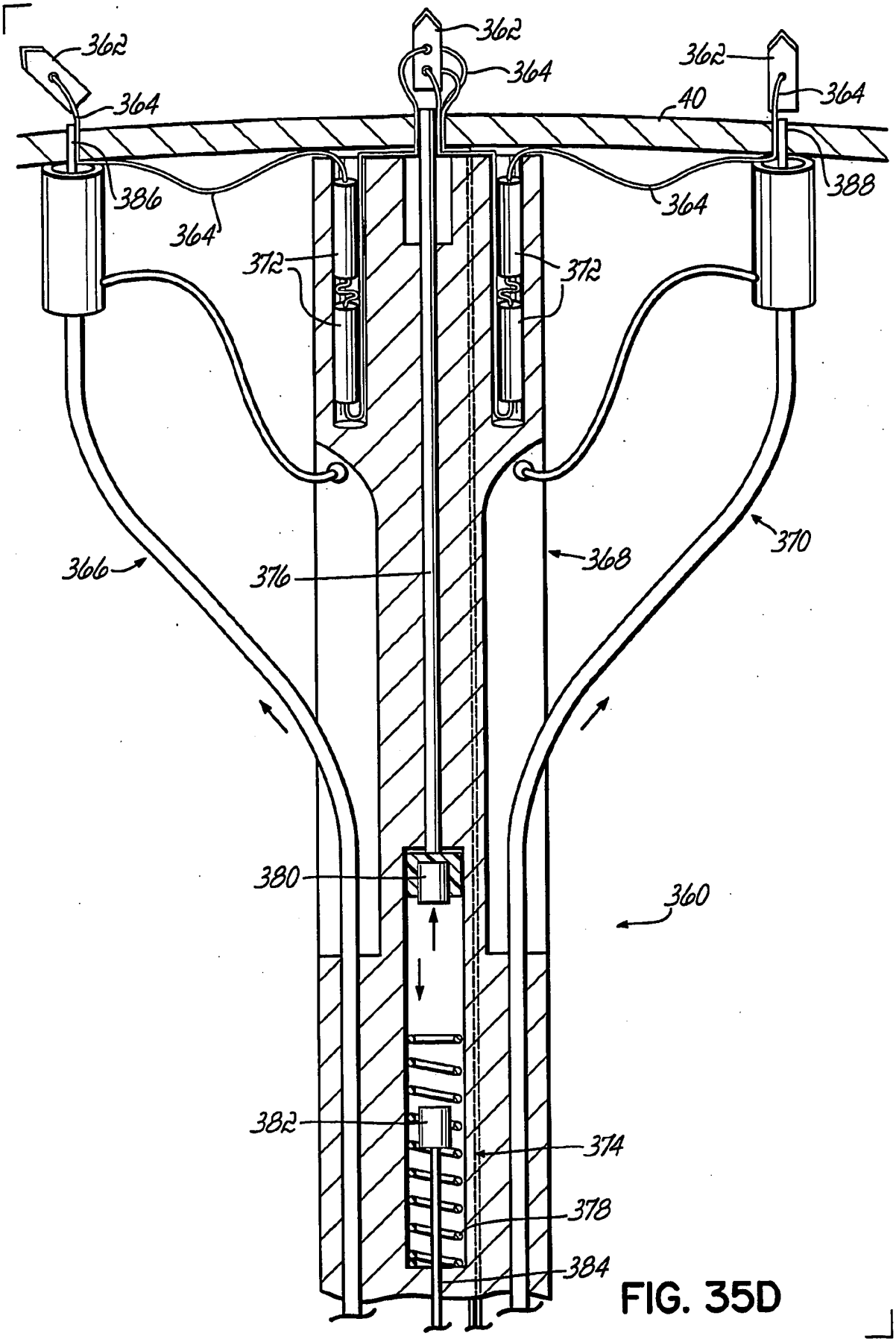
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FIG. 35D

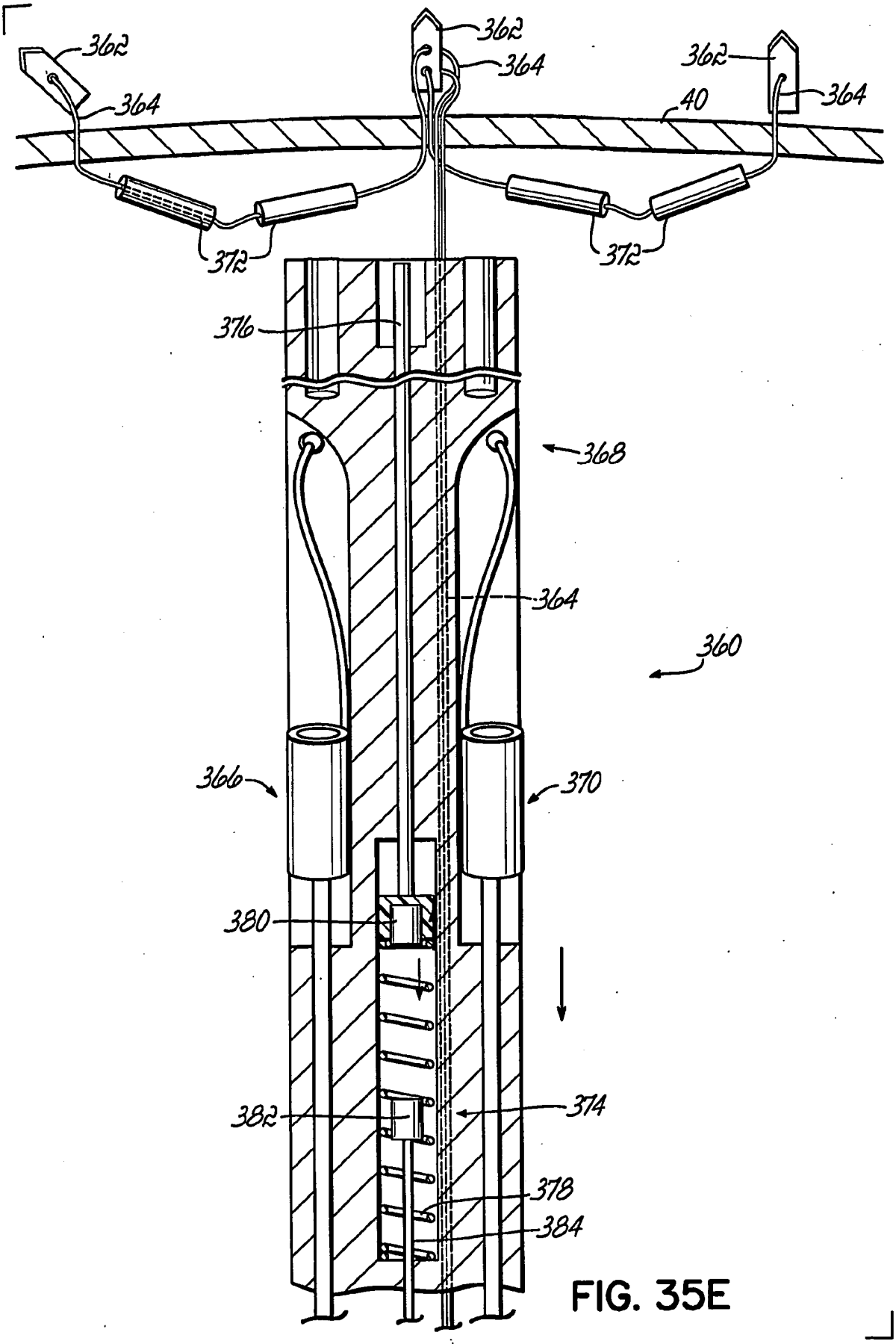
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FIG. 35E

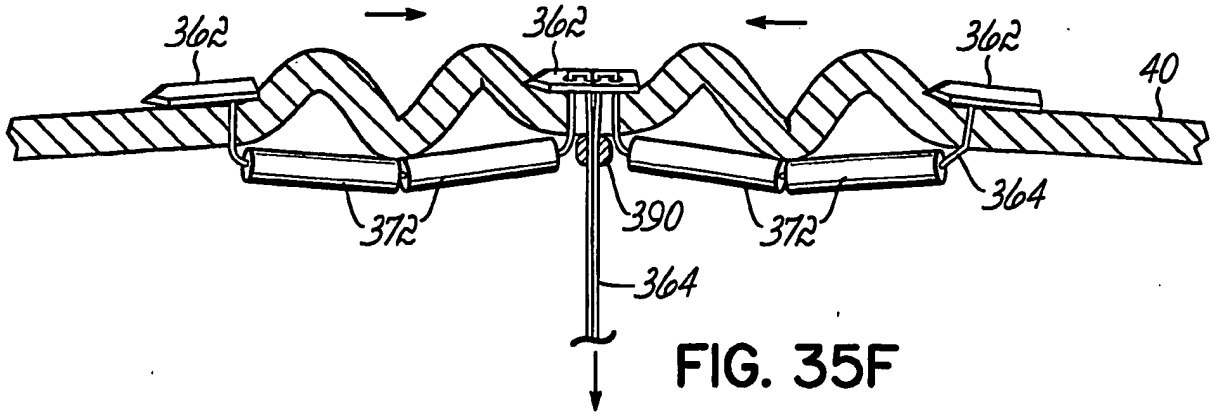

FIG. 35F

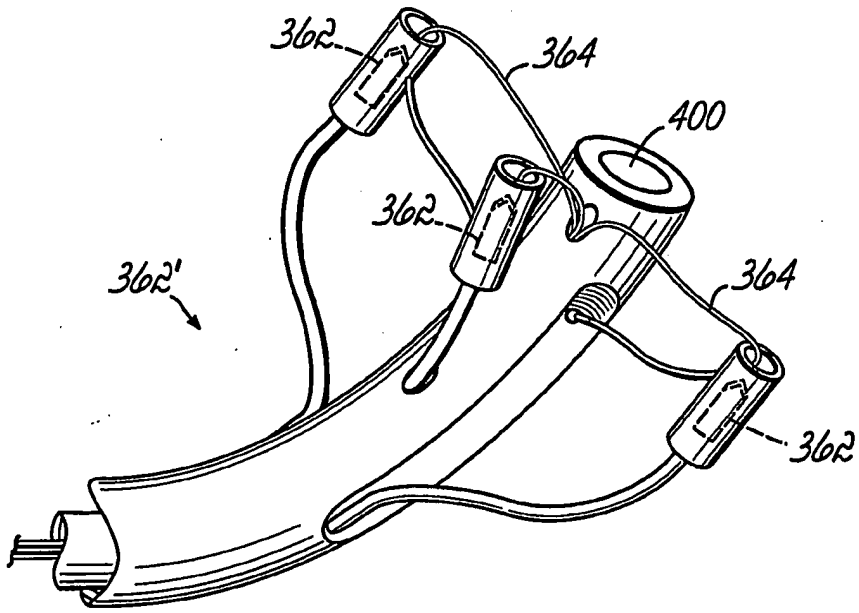

FIG. 36

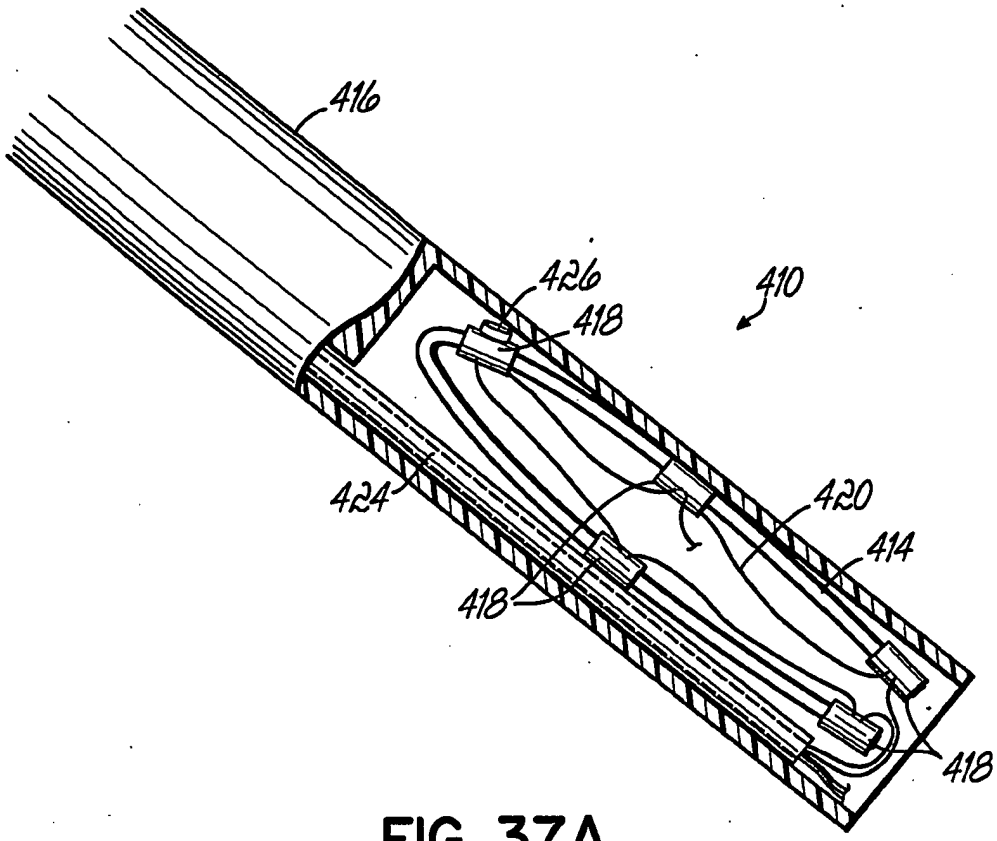

FIG. 37A

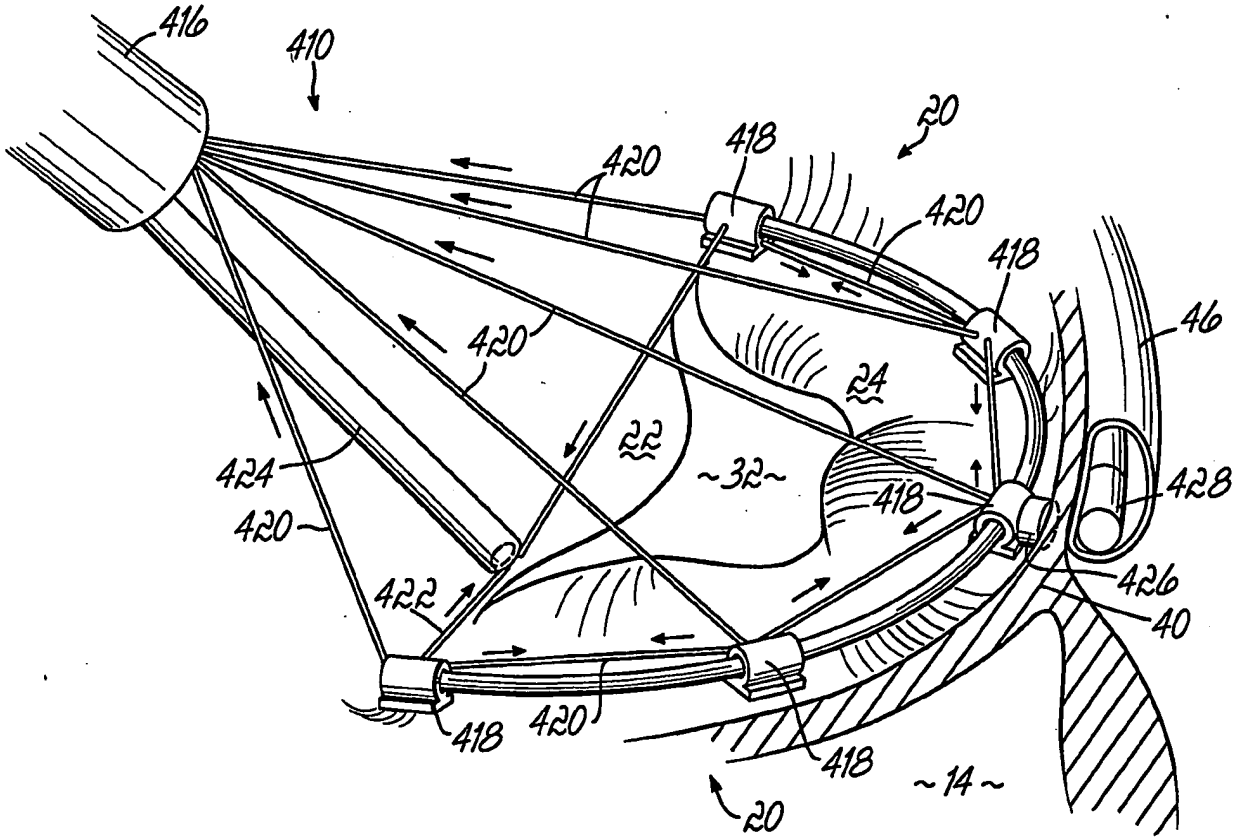

FIG. 37B

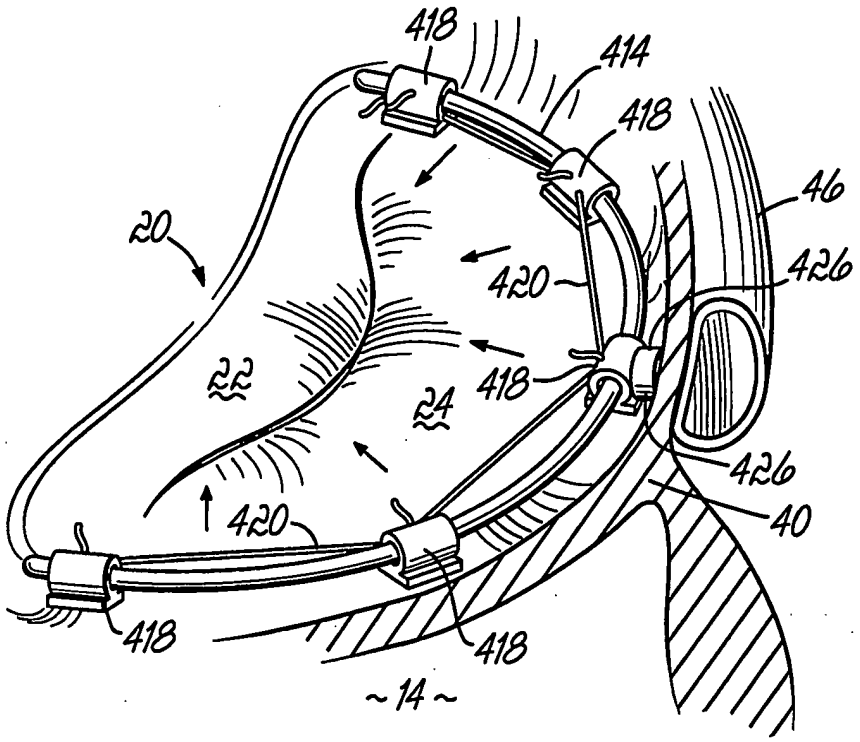

FIG. 37C

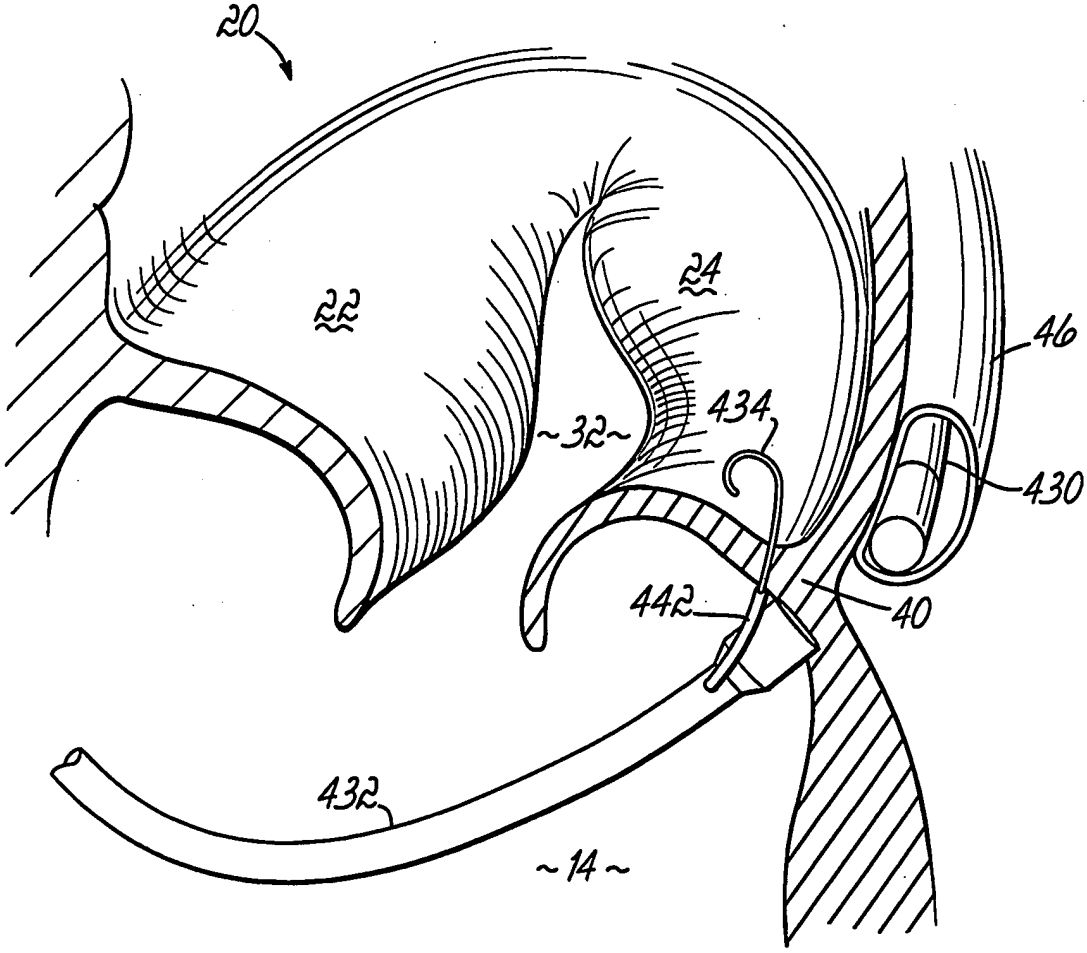

FIG. 38A

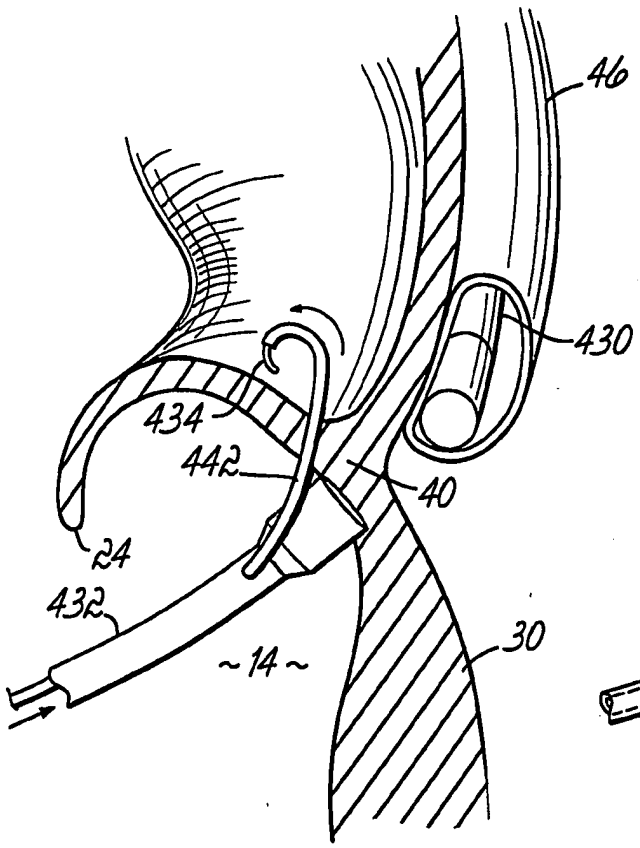

FIG. 38B

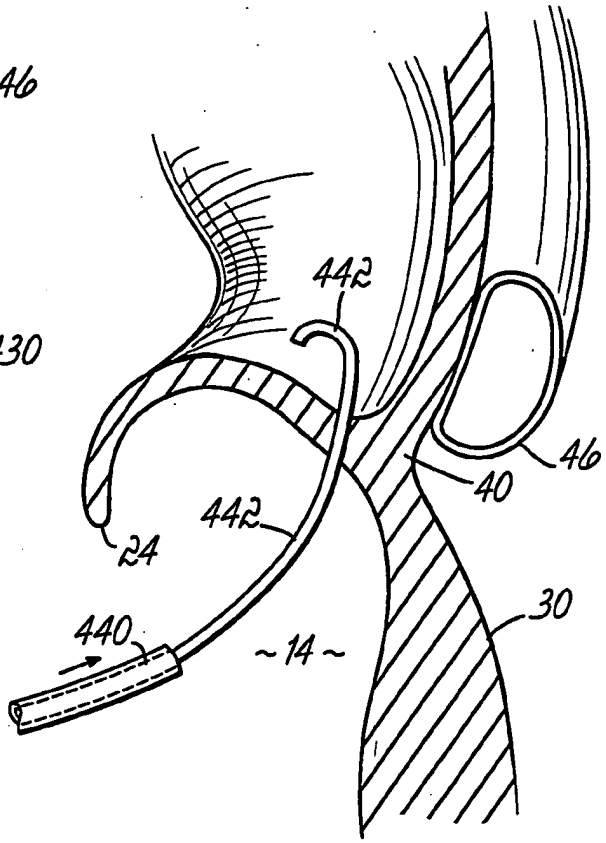

FIG. 38C

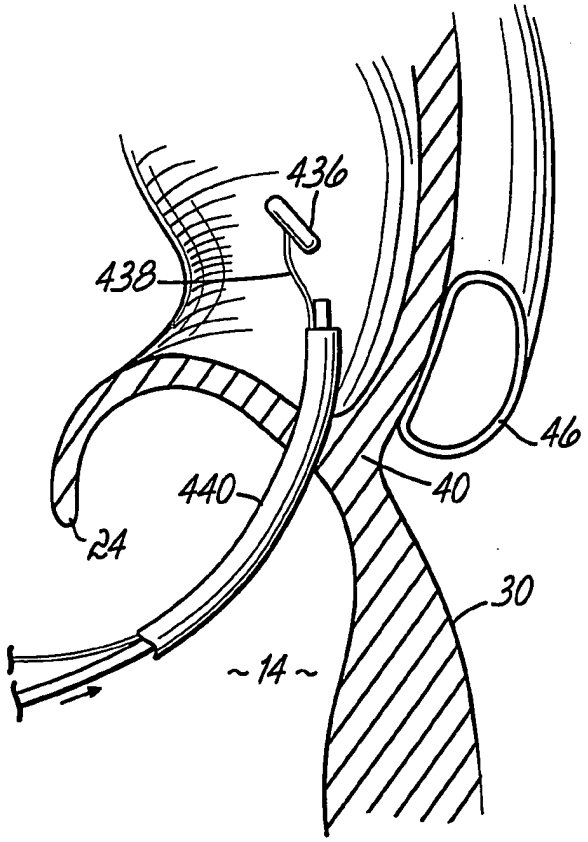

FIG. 38D

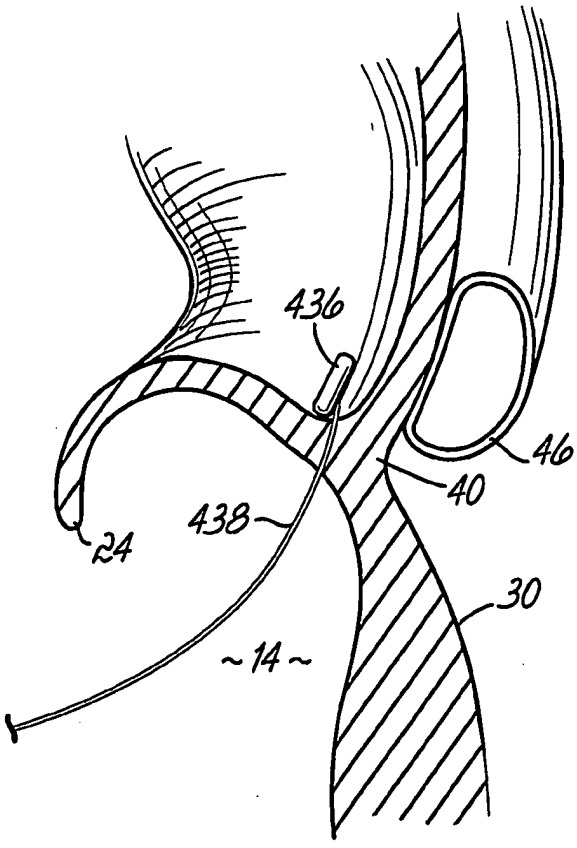

FIG. 38E

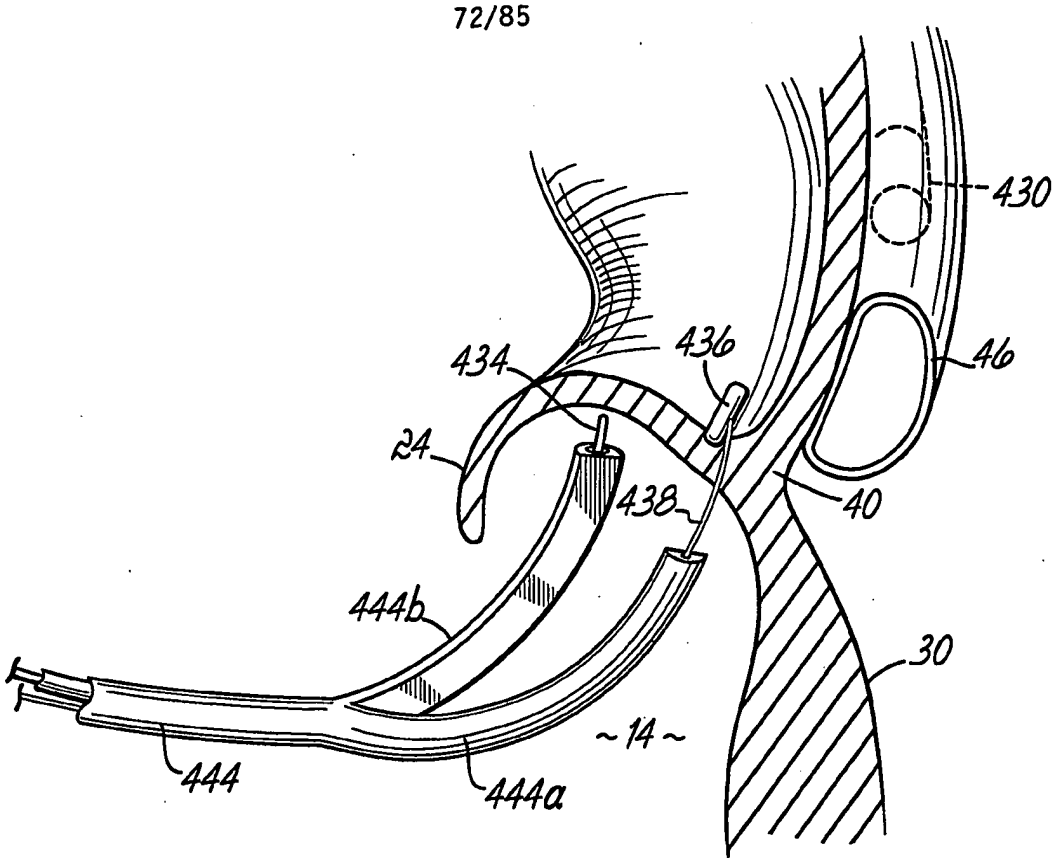

FIG. 38F

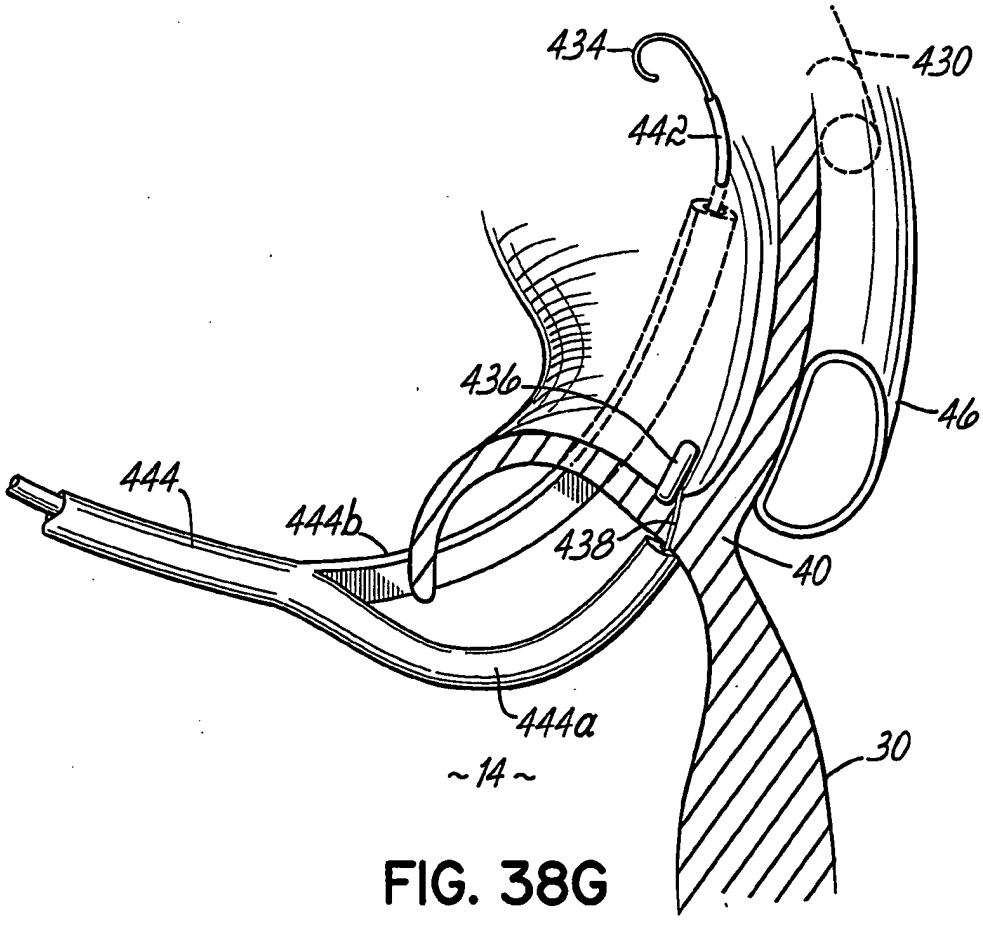

FIG. 38G

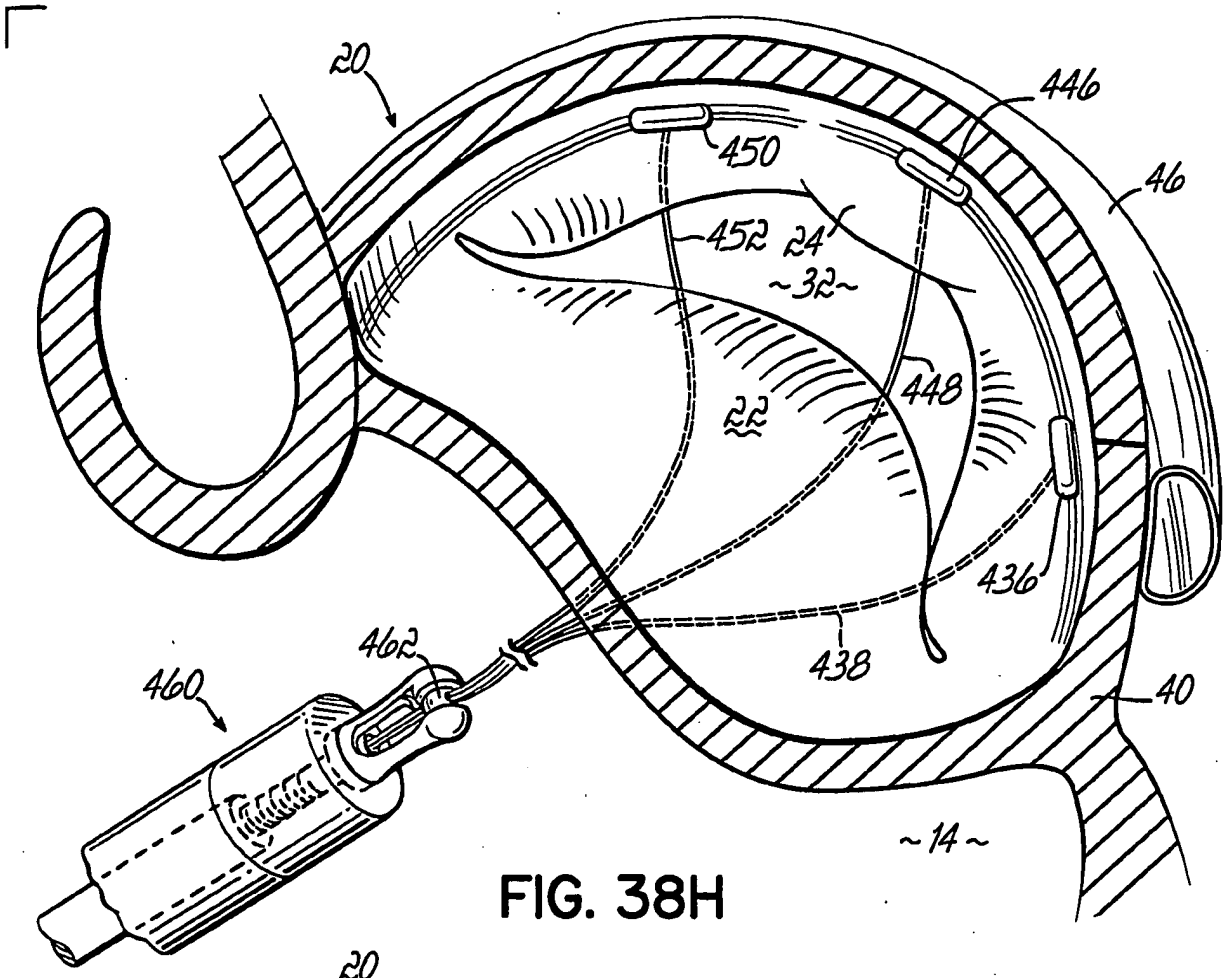

FIG. 38H

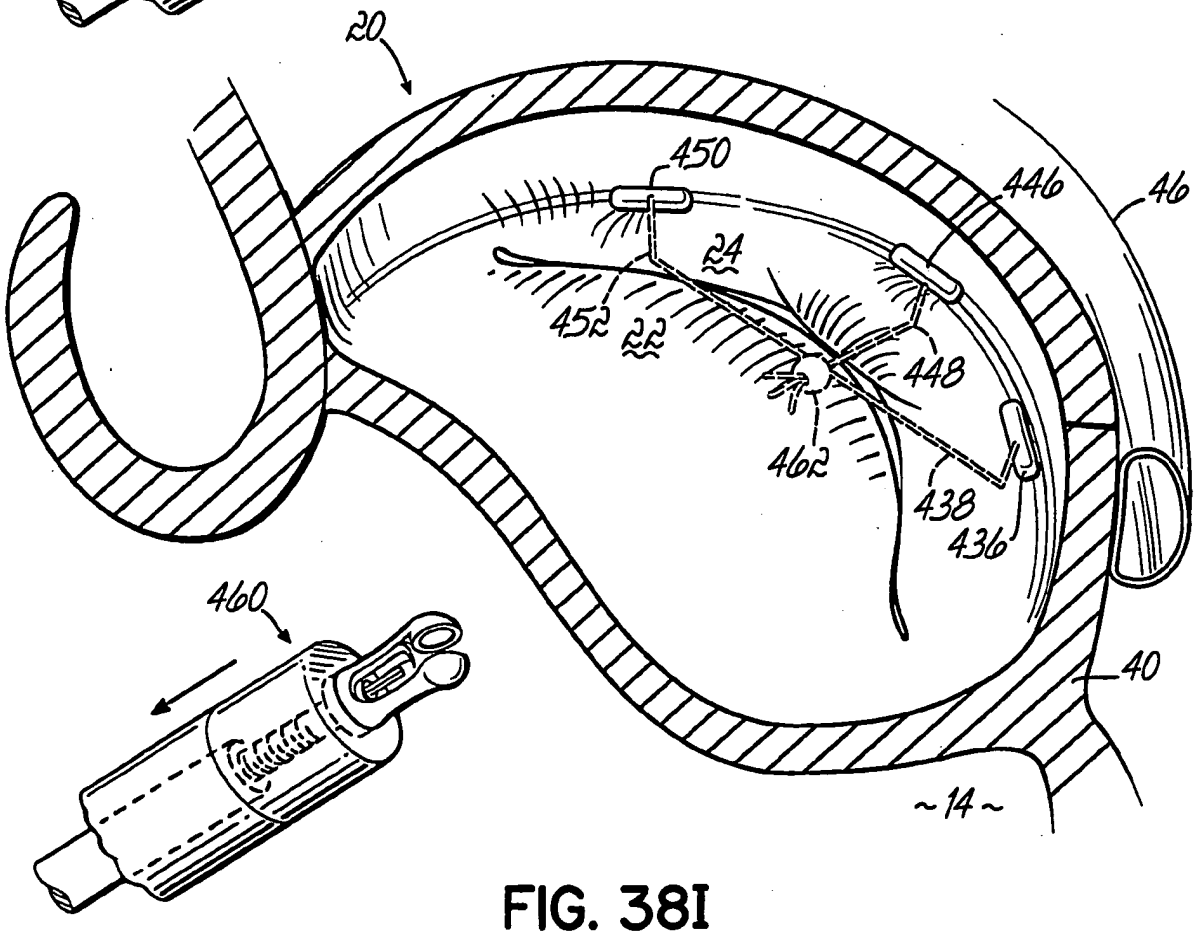

FIG. 38I

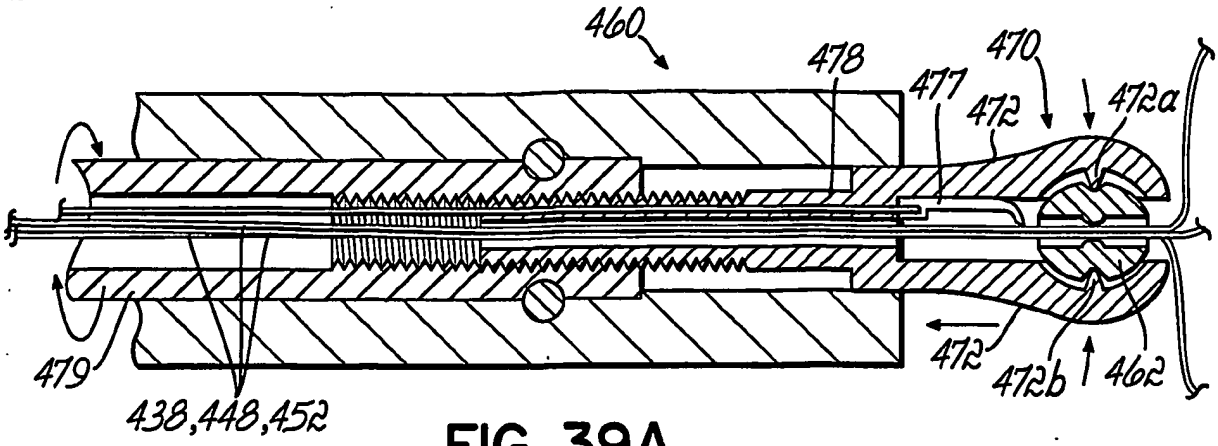

FIG. 39A

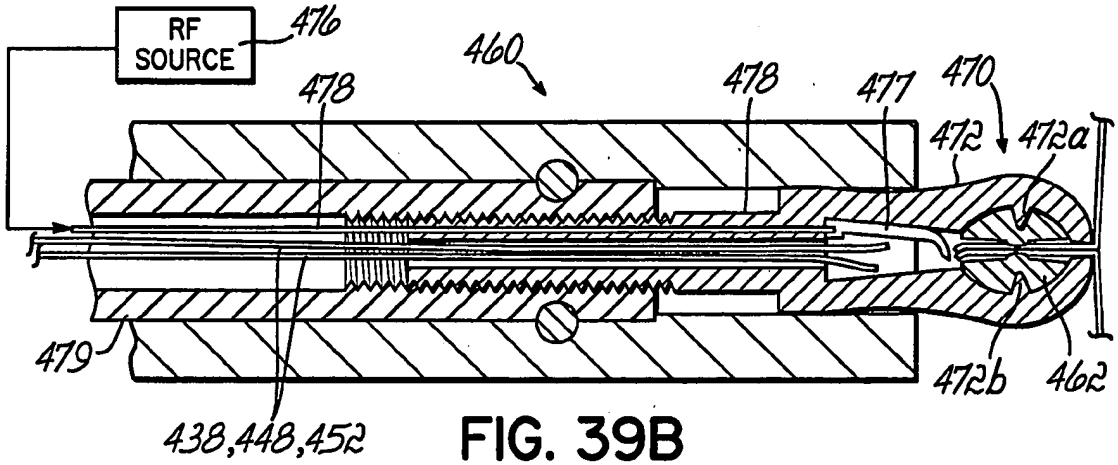

FIG. 39B

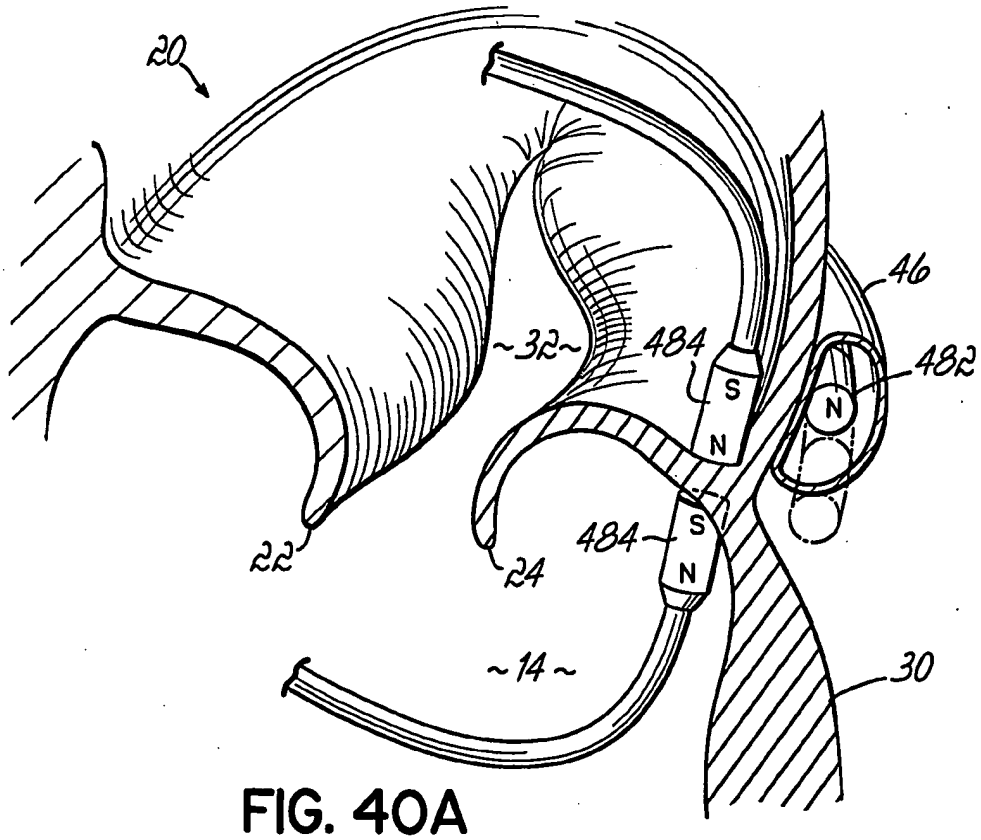

FIG. 40A

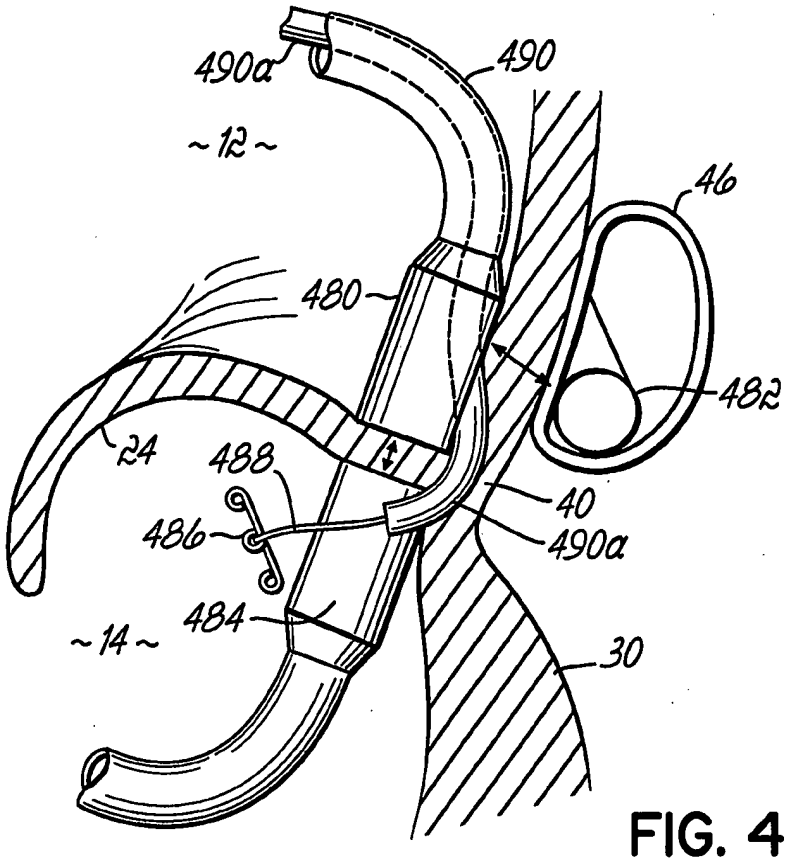

FIG. 40B

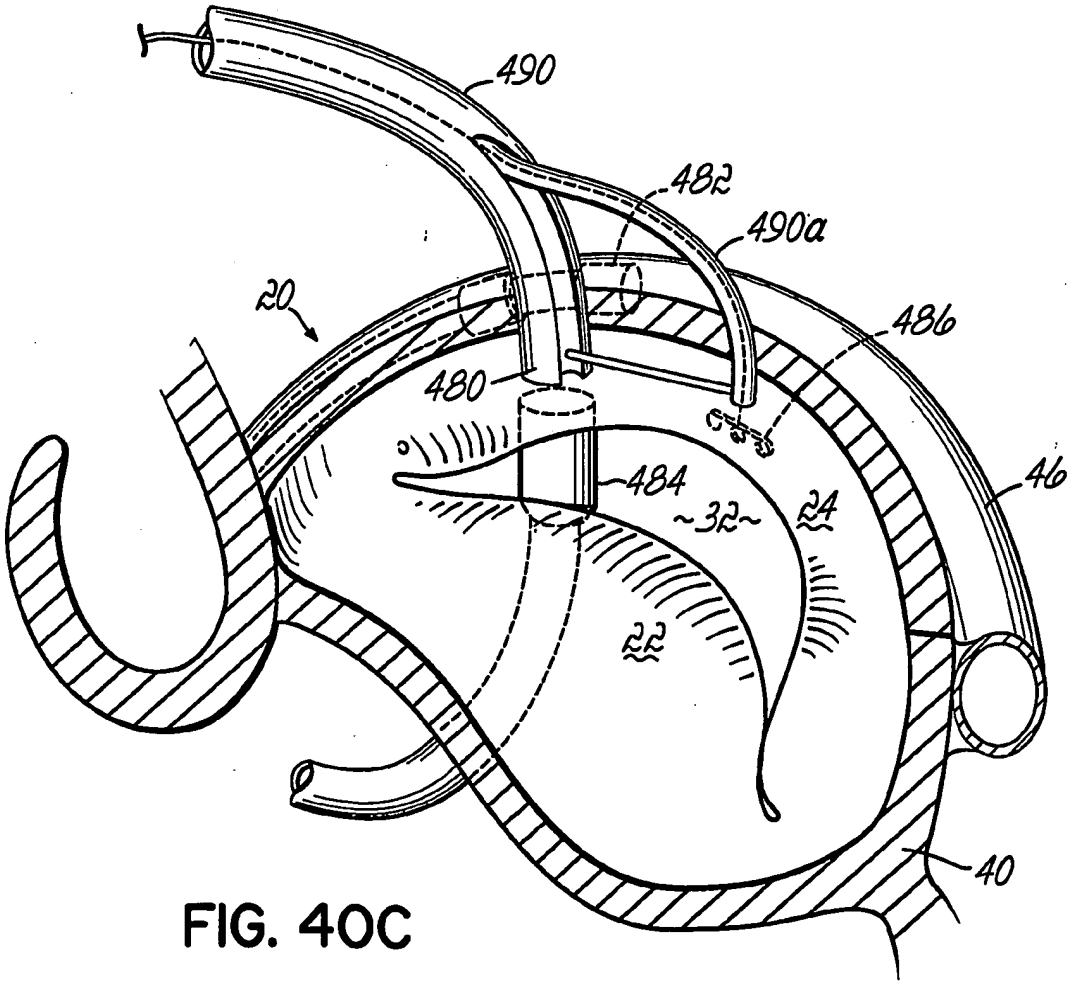

FIG. 40C

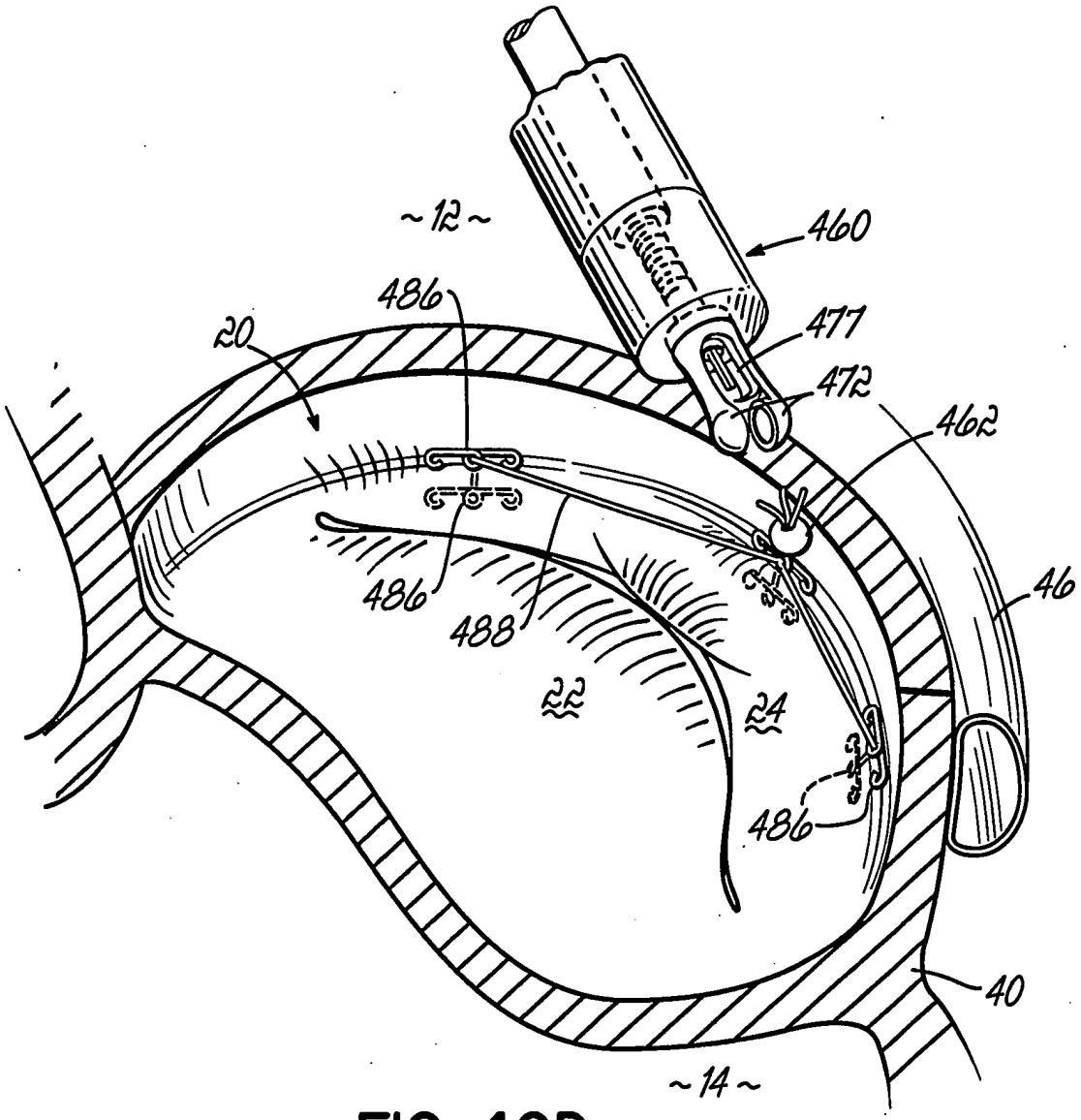

FIG. 40D

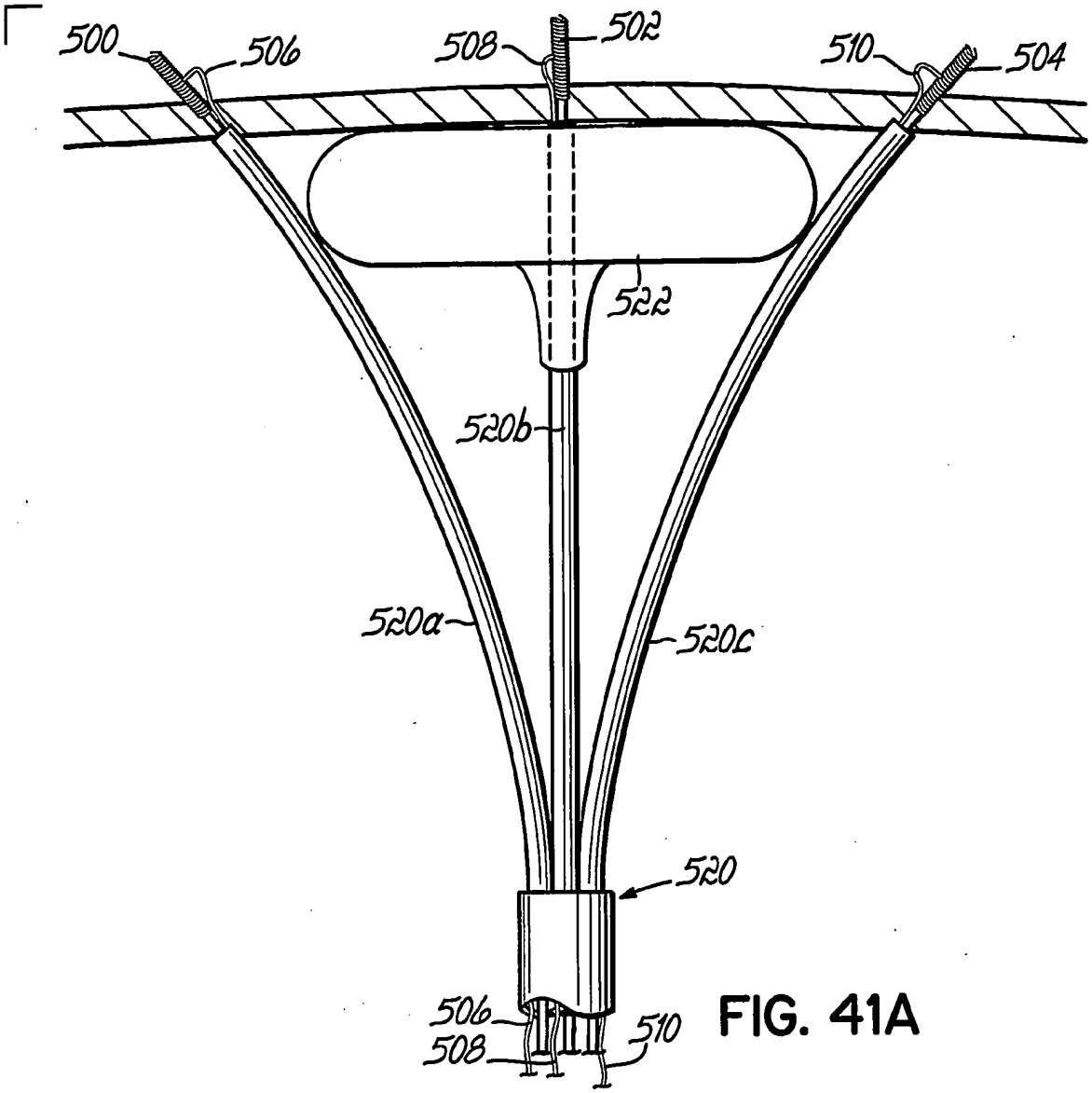

FIG. 41A

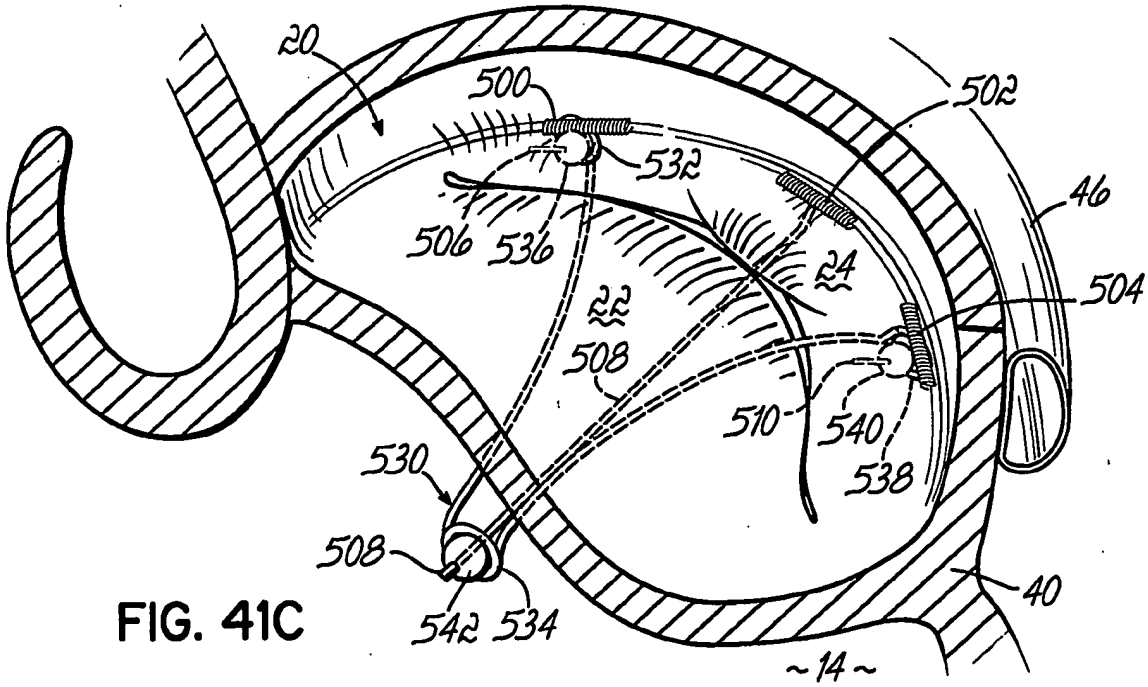

FIG. 41C

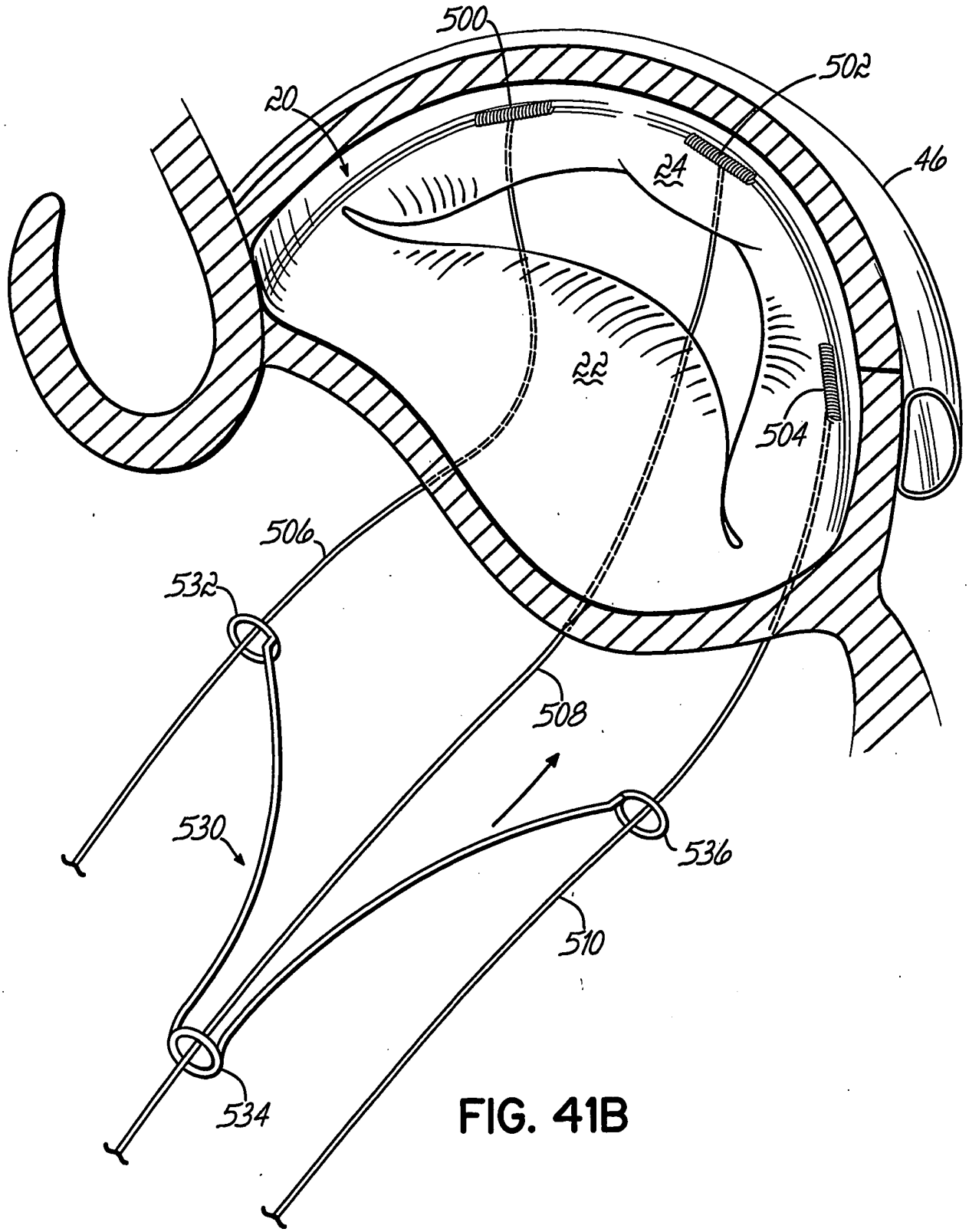

FIG. 41B

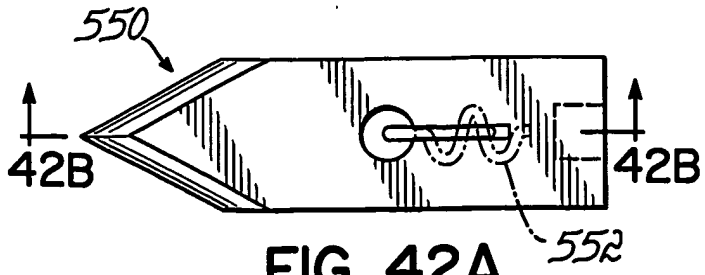

FIG. 42A

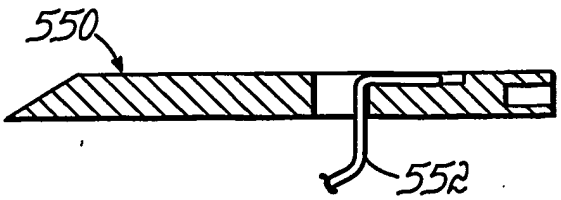

FIG. 42B

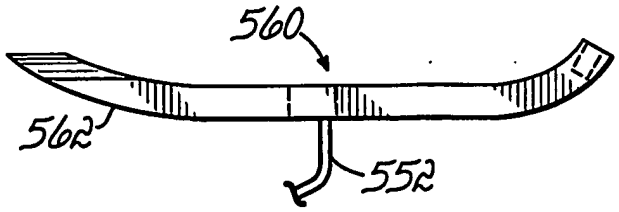

FIG. 43

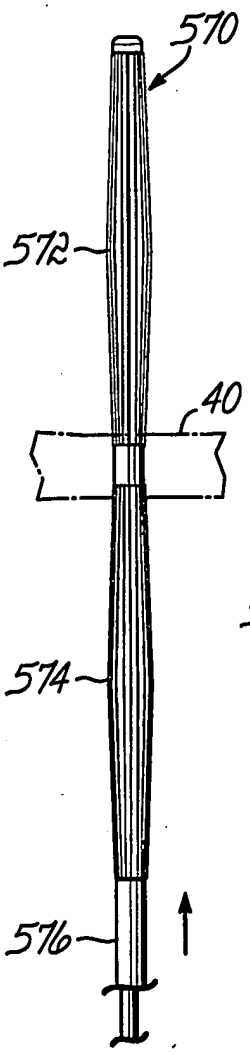

FIG. 44A

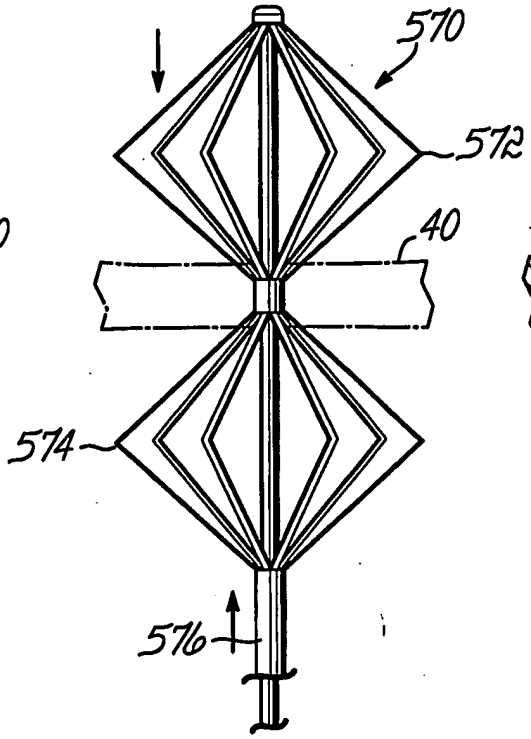

FIG. 44B

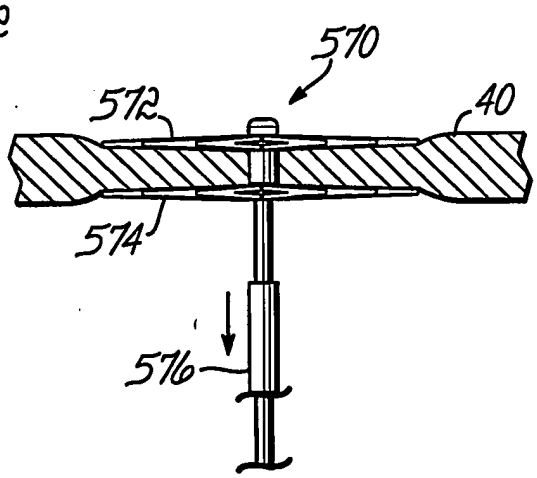

FIG. 44C

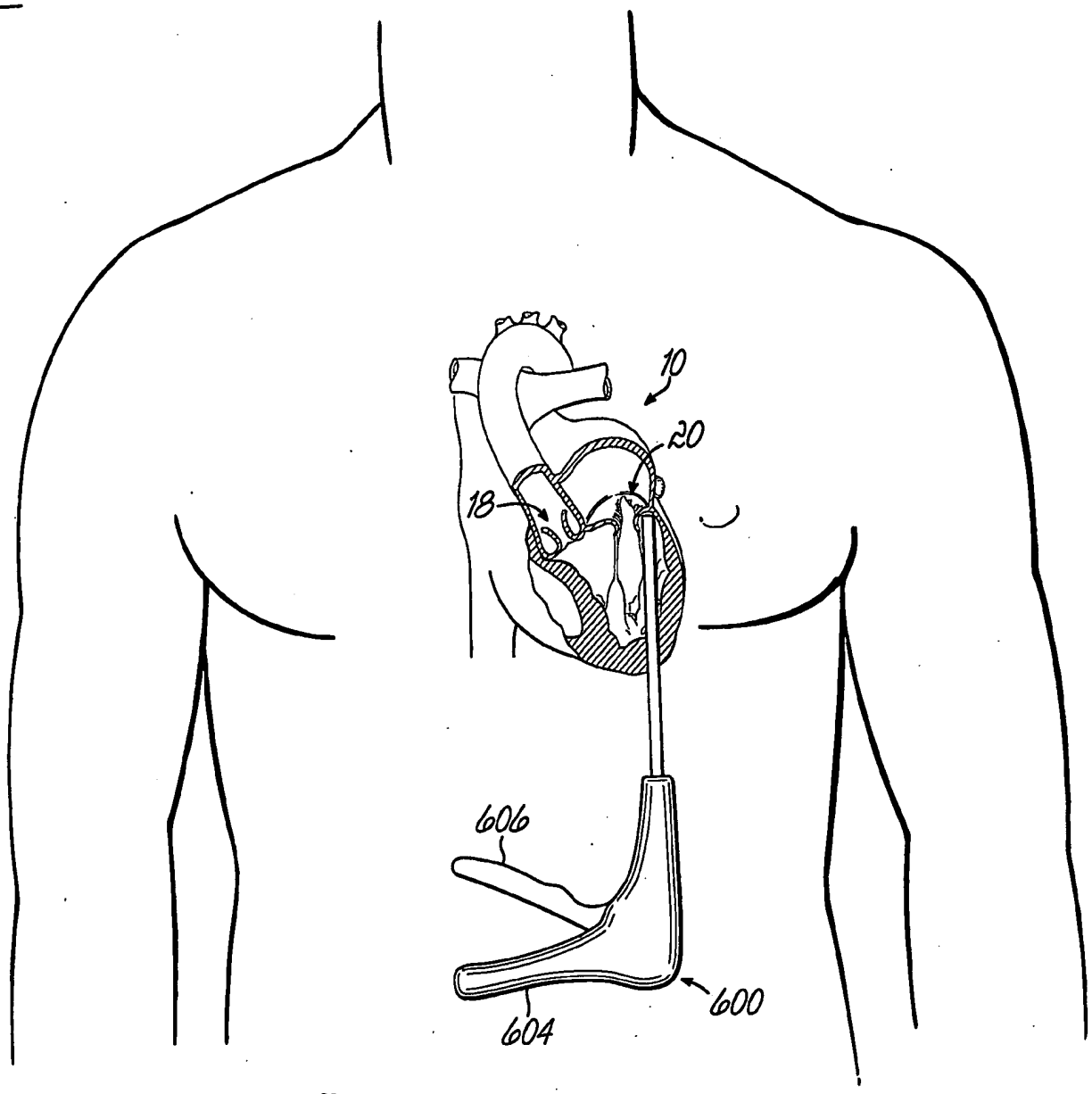

FIG. 45A

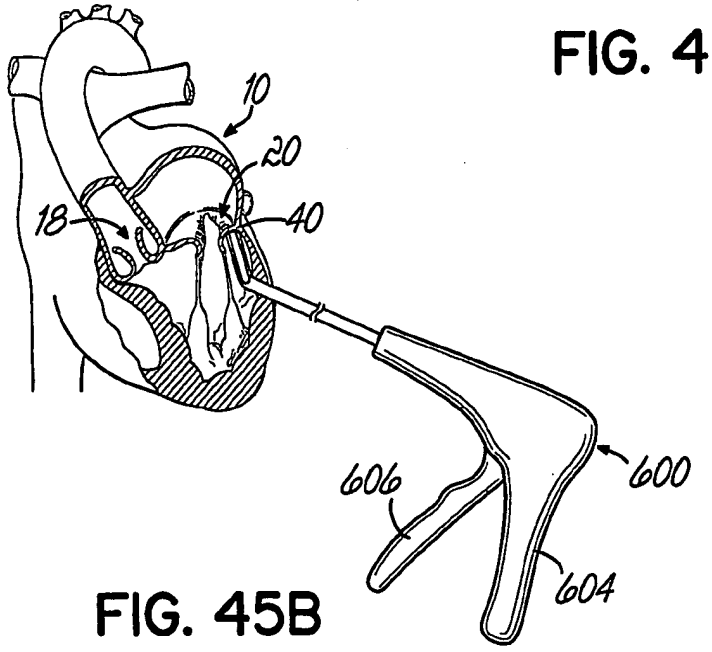

FIG. 45B

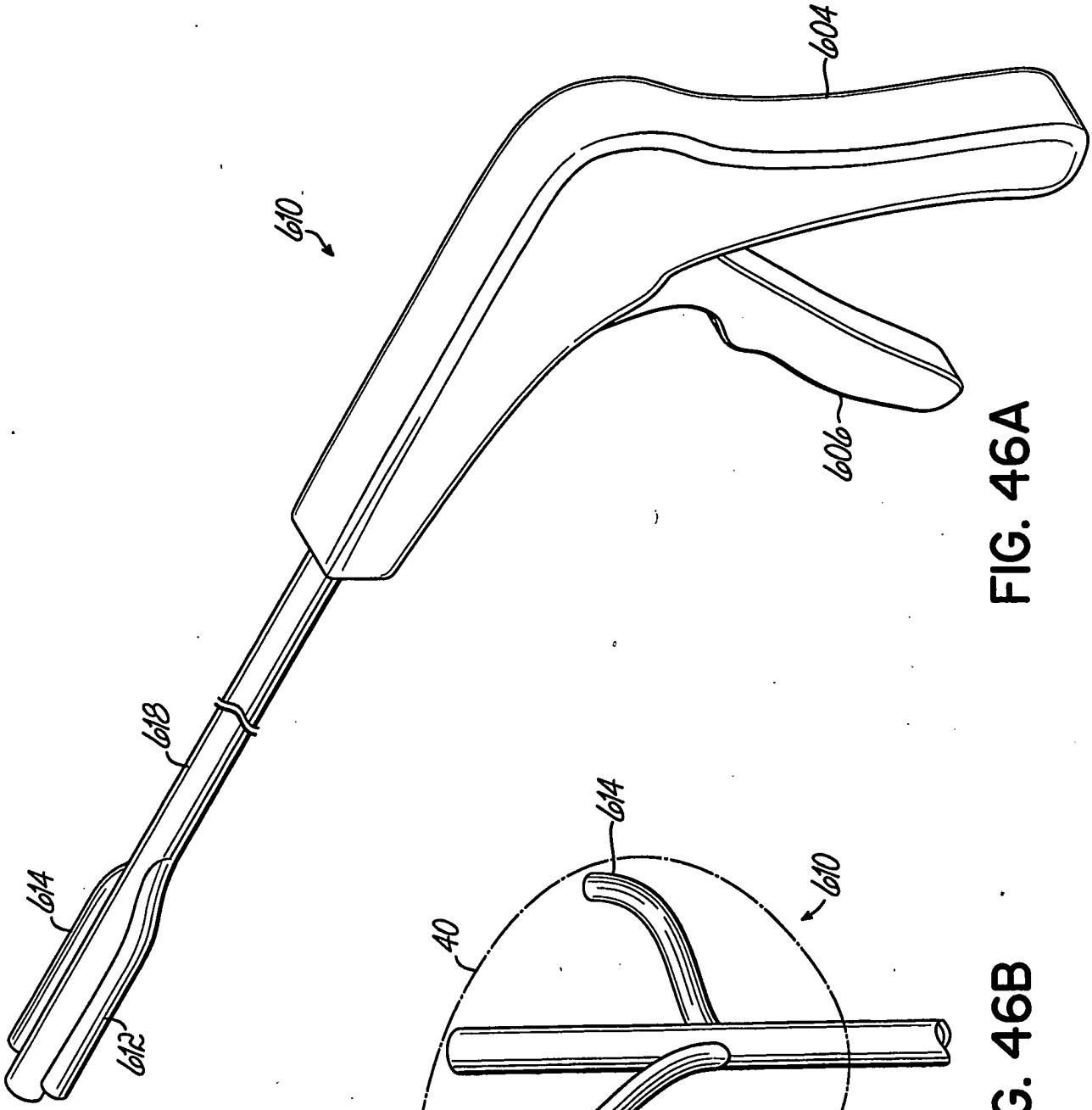

FIG. 46A

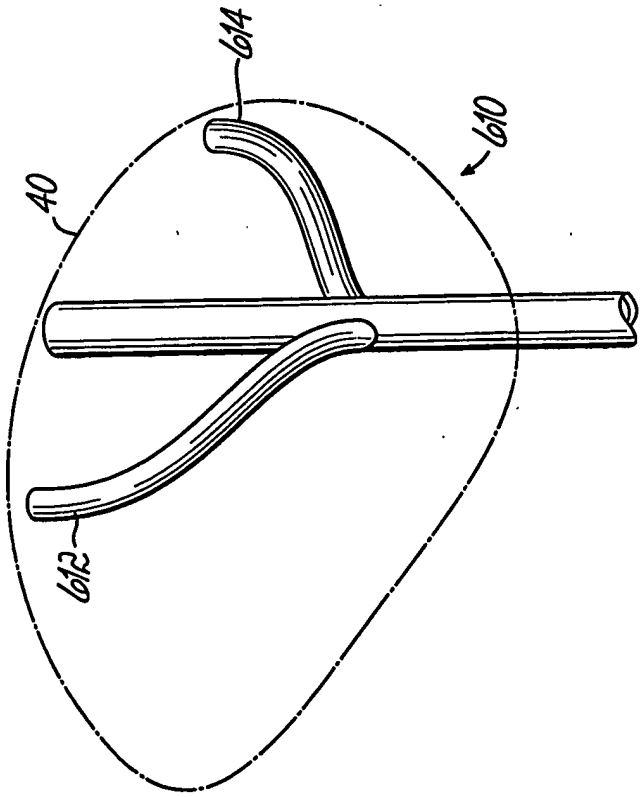

FIG. 46B

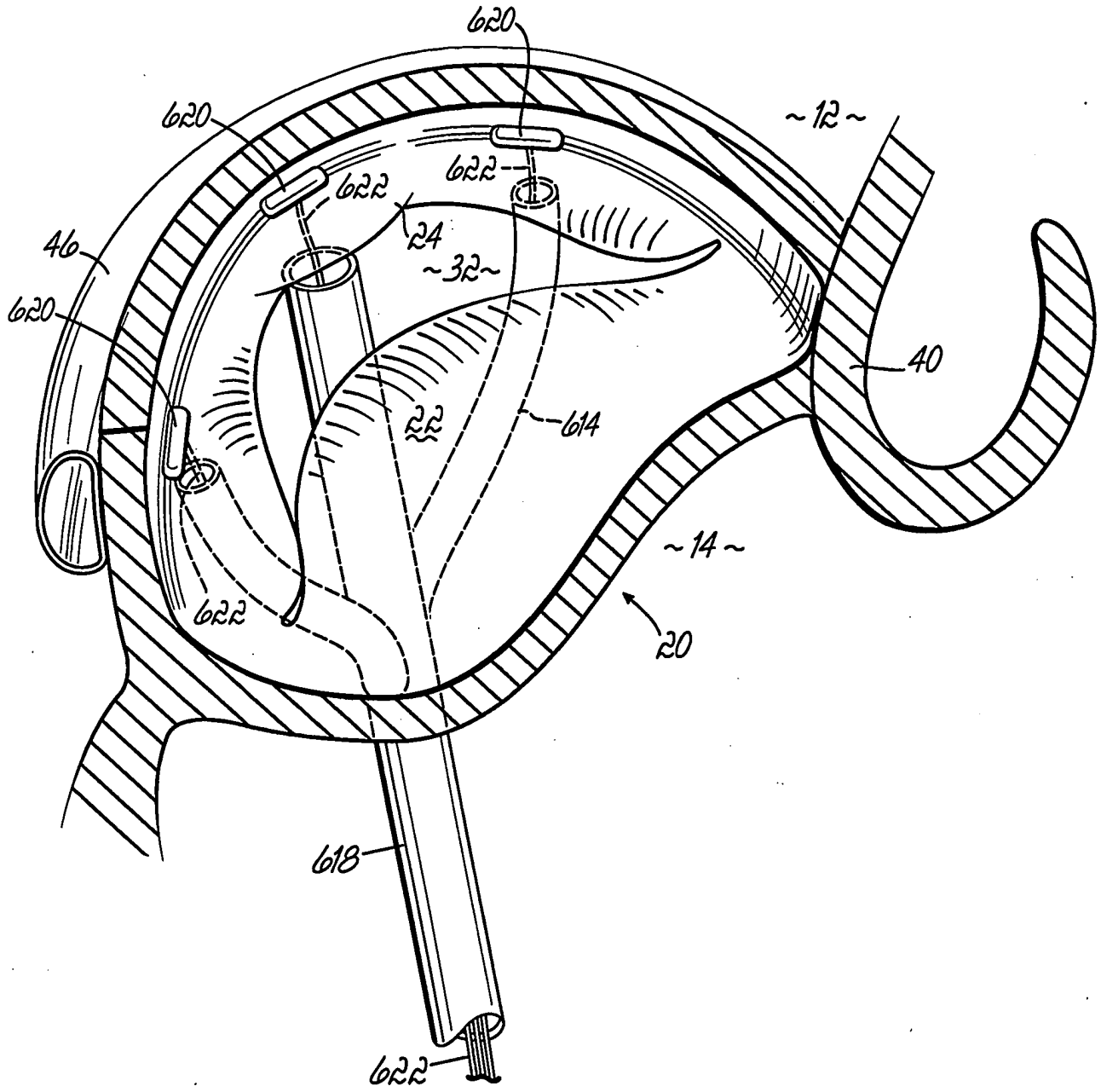

FIG. 47A

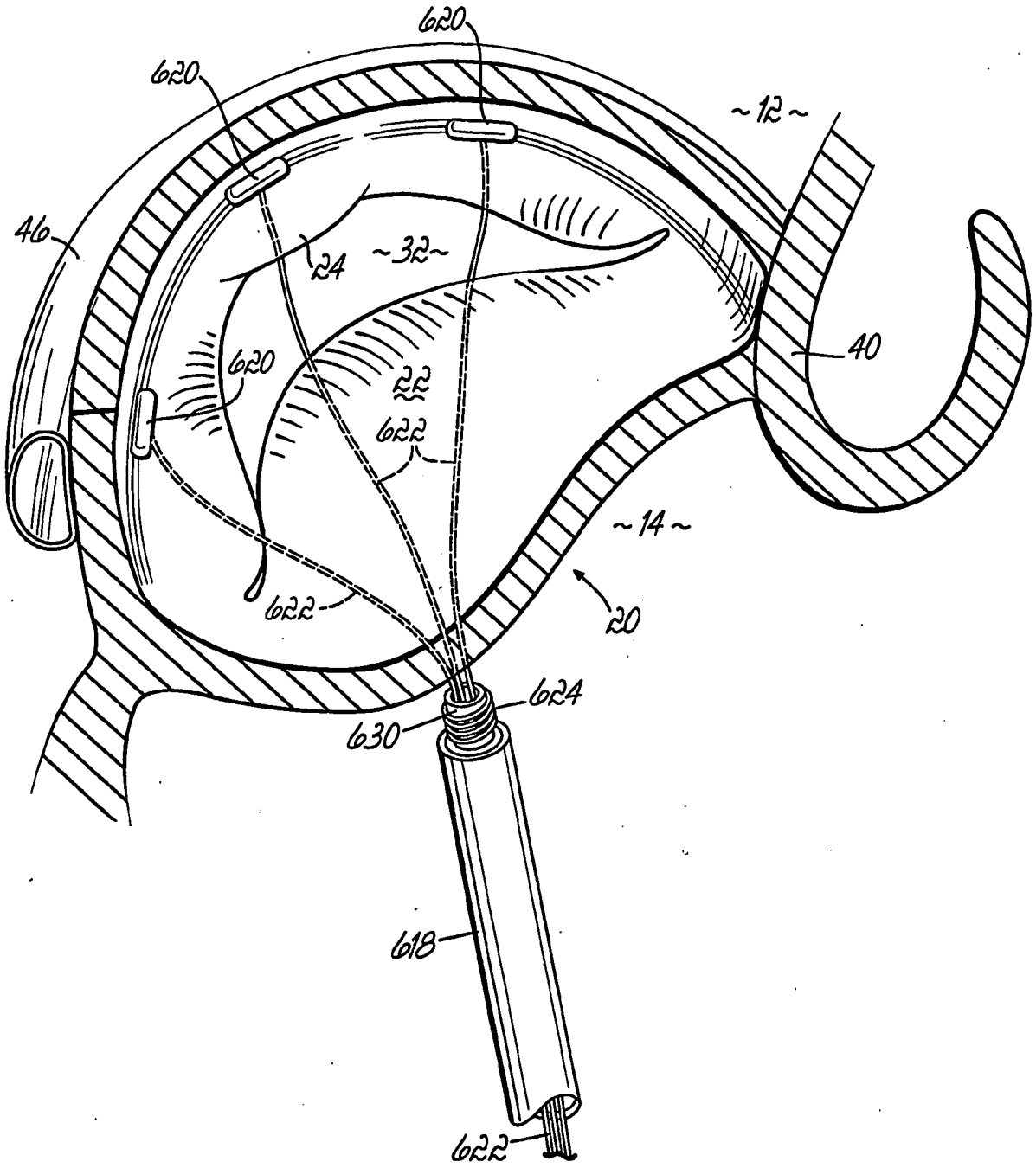

FIG. 47B

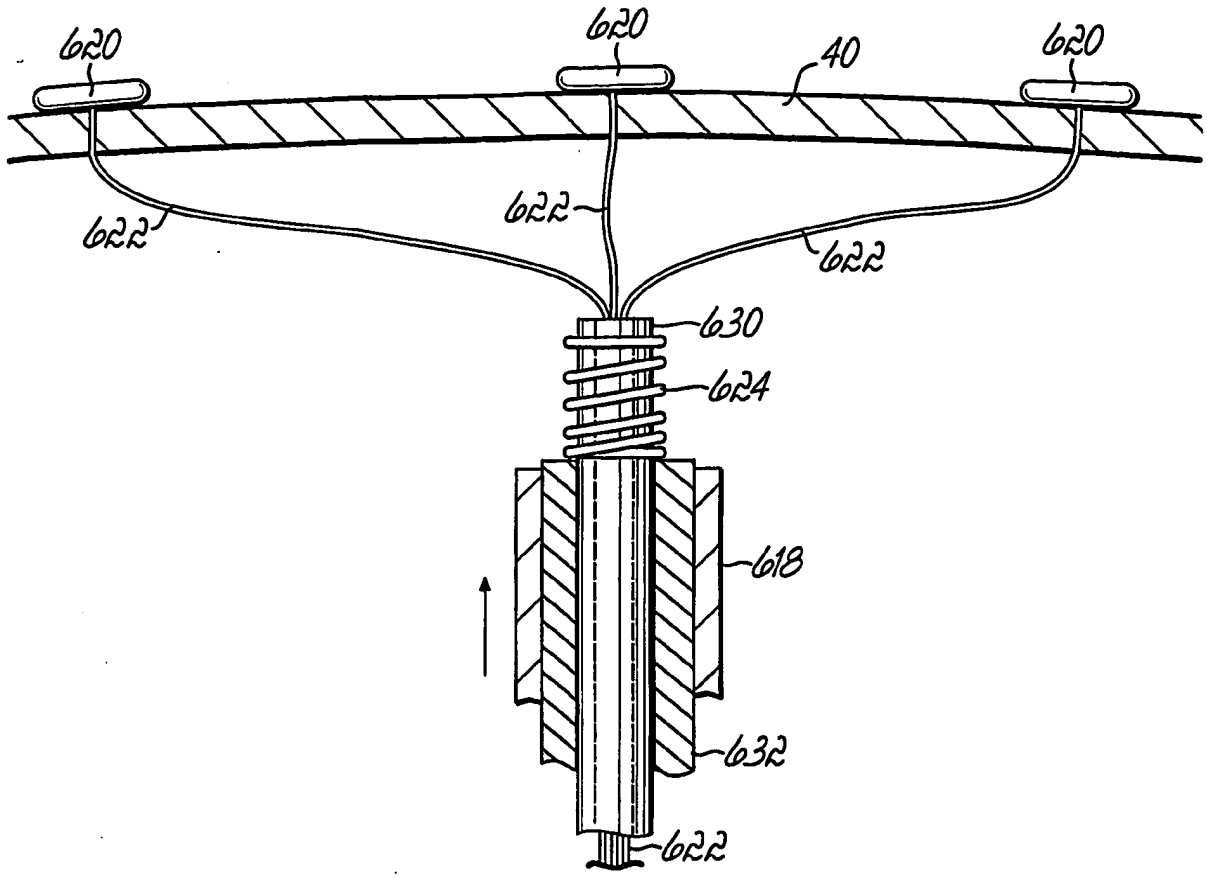

FIG. 47C

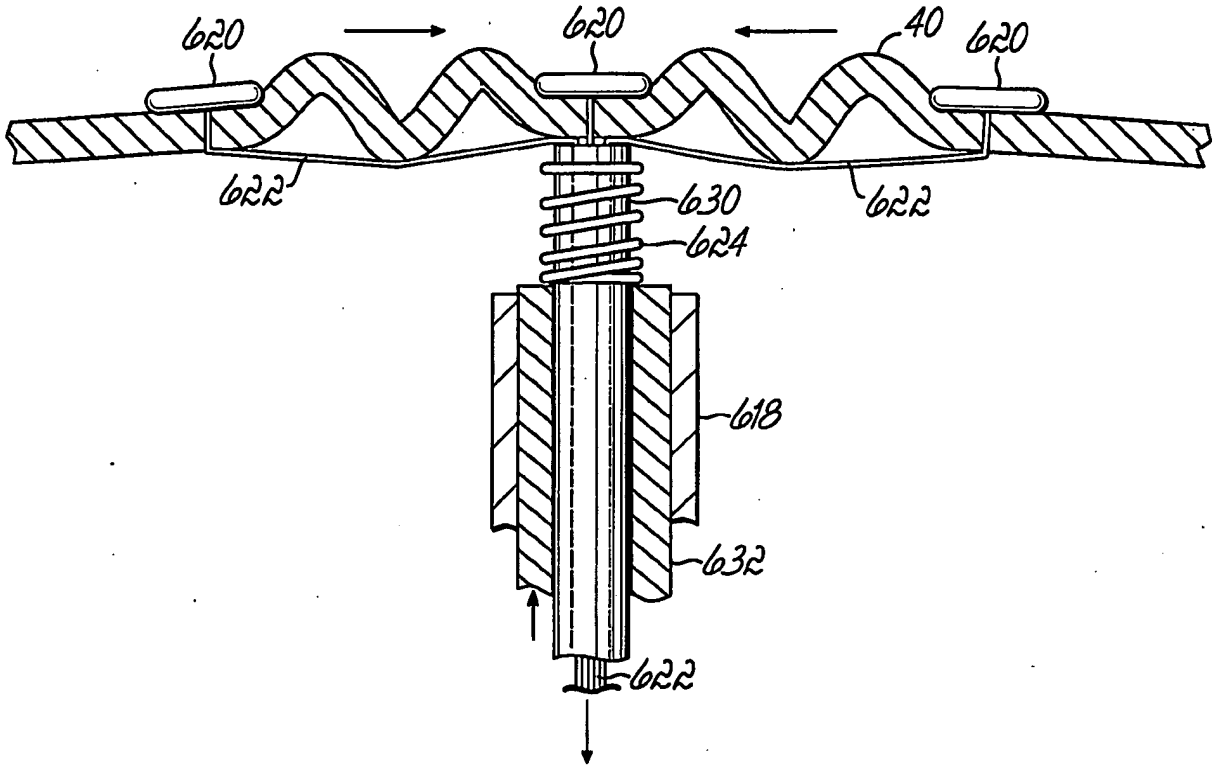

FIG. 47D

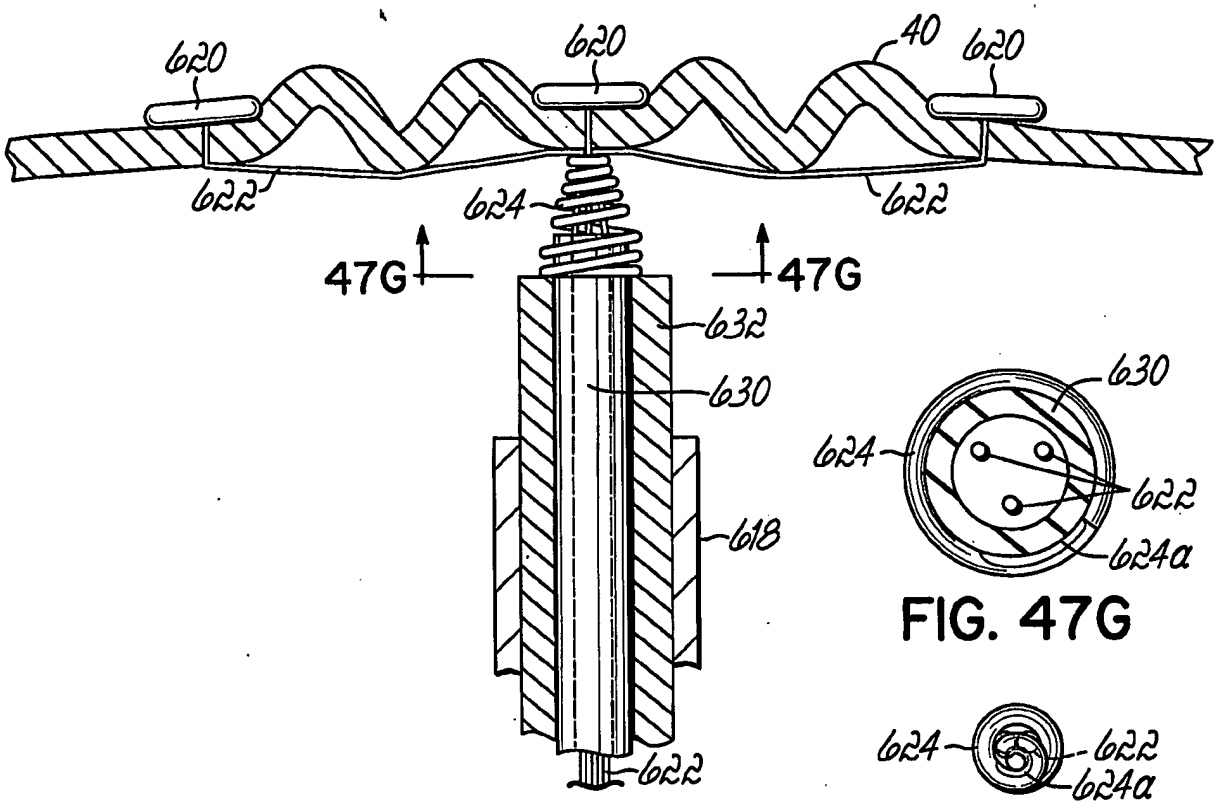

FIG. 47E

FIG. 47G

FIG. 47H

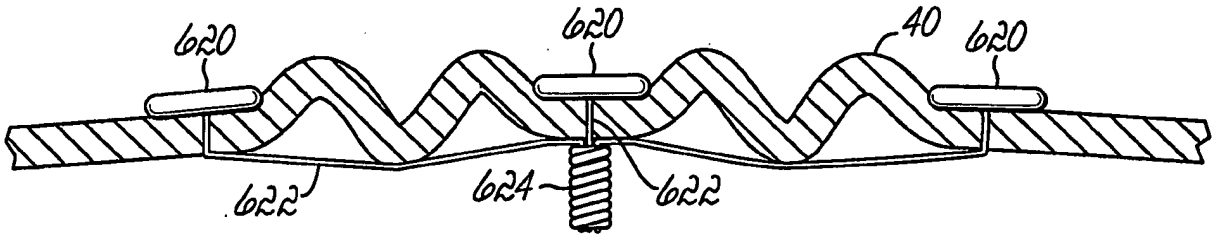

FIG. 47F

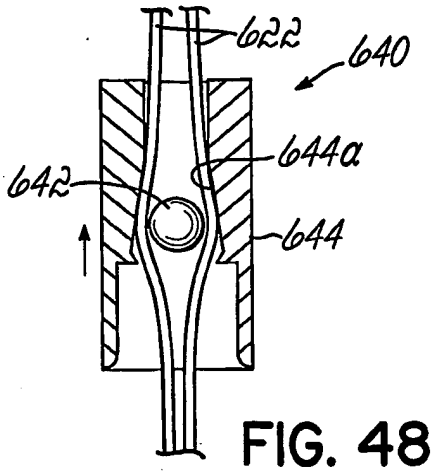

FIG. 48A

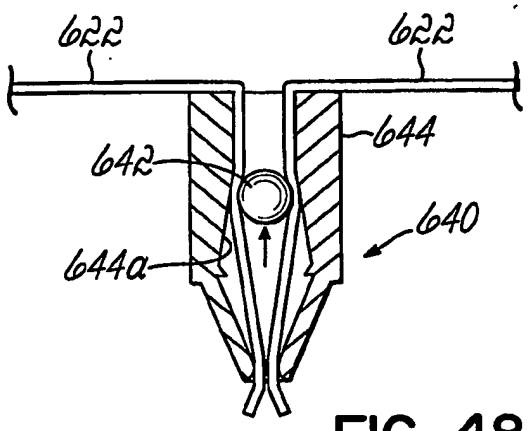

FIG. 48B